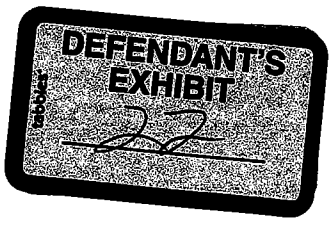
EXHIBIT 22



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION REPORT

DIGOXIN TABLETS, 0.25 mg
4,200,000 TABLETS

BATCHES 4330A, 4336A, and 4337A

MPR NO. 14602 Revision No. 00

Prepared by: _____

Date Prepared: 12/22/94

Approved by:

_____
Quality Assurance Director

Date: 1/5/95

_____
Manufacturing Operations Director

Date: 1/3/95

_____
Regulatory Affairs Director

Date: 1/5/95

_____
Quality Control Director

Date: 1/4/95

_____
VP Operations

Date: 1-4-95

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION SUMMARY

PRODUCT DIGOXIN TABLETS, 0.25 mg BATCH 4330A
4336A
4337A

The following comments apply to the three 4,200,000 tablet validation batches produced in this series.

This report includes data through Compression, which is the finished dosage form.

The process used to produce this batch follows exactly that shown in the normal batch record. Copies of the actual batch records are available in the file.

The data supporting the validation of the analytical methods used may be found in the Analytical Method Validation Report issued for this product.

A copy of the protocol to be followed for this project is included.

Evaluation of the data includes calculation of the Process Capability Index, Cp, when appropriate. Cp is a measure of the ability of a process to produce material that is all within the specification range. It verifies that the entire distribution curve for the data collected falls within the allowable limits. The following equation is used.

$$Cp = \frac{(\text{Upper Limit} - \text{Lower Limit})}{6 \times \text{St. Dev.}}$$

Any value equal to or greater than 1 is acceptable.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

CONCLUSIONS AND OBSERVATIONS

All samples met the established acceptance criteria.

Based on these three batches, the process is considered validated and is acceptable for use.

The data verifies the initial acceptance criteria for all parameters. At this point no revision to any of these ranges will be made.

The final blends showed adequate uniformity for all batches. The resulting Cp value is 4.7, which is more than acceptable.

Content uniformity results are all within the acceptance criteria, and are essentially comparable to the blend results.

Results for both the final blends and content uniformity center around the label amount.

All Dissolution samples for the three batches met the USP requirements. The values for the three batches are comparable, however there is some variability within the individual batches.

The data for each protocol step follows a summary of that step, in the order in which it appears in the protocol.

Amide Pharmaceutical, Inc.

Process Validation

DIGOXIN TABLETS, 0.25 mg

Process Validation Summary

Batch Size - 4,200,000 Tablets

Test	Initial Limits	Batch	4330A	4336A	4337A	Combined	Final Limits
Final Blend Assay (%)	85.0 - 115.0 %Th. (Ind.)	Average	101.0	101.5	101.4	101.3	85.0 - 115.0 %Th. (Ind.)
		Std Dev	0.8	1.1	1.3	1.1	
		Cp				4.7	
Compression Weight (g)	0.114 - 0.126 g	Average	0.119	0.120	0.120	0.120	0.114 - 0.126 g
		Std Dev	0.001	0.001	0.002	0.002	
		Cp				1.2	
Compression Hardness (KP)	2.0 - 8.0 kp	Average	5.0	5.3	4.9	5.1	2.0 - 8.0 kp
		Std Dev	0.4	0.5	0.4	0.5	
		Cp				2.1	
Compression Thickness (mm)	2.7 - 3.7 mm	Average	3.11	3.13	3.14	3.13	2.7 - 3.7 mm
		Std Dev	0.02	0.02	0.03	0.03	
		Cp				6.6	
Compression Friability (%)	NMT: 1.0 %	Average	0.1	0.1	0.1	0.1	NMT: 1.0 %
		Std Dev	0.0	0.04	0.1	0.04	
Compression Disintegration (min)	N/A	Average	2.7	2.8	2.8	2.8	N/A
		Std Dev	0.5	0.8	0.8	0.6	
Compression Content Uniformity (%)	85.0 - 115.0 % RSD NMT: 6.0 %	Average	100.6	99.8	100.5	100.3	85.0 - 115.0 % RSD NMT: 6.0 %
		Std Dev	1.4	1.5	1.8	1.6	
		Cp				3.1	
Compression Dissolution (%) 15 min.	NMT: 90% (ind.)	Average	82.0	77.4	81.6	80.3	NMT: 90% (ind.)
		Std Dev	1.9	3.5	2.0	3.3	
Compression Dissolution (%) 60 min.	NLT: 80% (avg)	Average	96.1	93.4	96.1	95.2	NLT: 80% (avg)
		Std Dev	2.9	4.0	4.6	4.0	

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

PROTOCOL STEP - RAW MATERIALS

The raw materials used will be tested, as stated in the protocol, in accordance with approved specifications and methods. In addition, bulk density, tamped density and particle size distribution will be included.

ACCEPTANCE CRITERIA

Parameters normally evaluated will be compared to the current specifications. The density and particle size data will be gathered and used to formulate guidelines when sufficient data is accumulated.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

All data is acceptable.

Any differences noted do not appear to have any effect on finished product quality.

Particle size determinations were run on two different pieces of equipment. One is a "Ro-Tap" type unit and the other a Micron Air Jet Sieve. For samples run on the "Ro-Tap" the coarser mesh screen is listed first.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Usage Chart

Item #	Item Name	Batch # 4330A P.O. #	Batch # 4336A P.O. #	Batch # 4337A P.O. #
3115	Corn Starch, NF	4025	4025	4025
0111	Digoxin, USP	3929	3929 & 3929-1	3929-1
3000	Croscarmellose Sodium, NF	4026	4026	4026
3051	Lactose Hydrous Impalpable, NF	4028-1	4028-1	4028-1
3088	Starch Pregelatinized, NF	4027	4027	4027
3059	Microcrystalline Cellulose, NF	4023	4023	4023
3050	Lactose Anhydrous, NF	4015	4015	4015
3089	Stearic Acid, NF	3910	3910	3910
3081	Silicon Dioxide, NF	3696	3696	3696

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Comparison - Corn Starch, NF (3115)

P.O. #	4025
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
MICROBIAL LIMITS	Passes Test	Passes
PH	4.5 - 7.0	5.7
LOSS ON DRYING	NMT 14.0%	2.1%
RESIDUE ON IGNITION	NMT 0.5%	0.1%
IRON	NMT 0.002%	< 0.002%
OXIDIZING SUBSTANCES	Passes Test	Passes
SULFER DIOXIDE	Passes Test	Passes
BULK DENSITY		0.52 g/mL
TAP DENSITY		0.72 g/mL
PARTICAL SIZE (US 325)	% Retained	3.9%
PARTICAL SIZE (US 200)	% Retained	2.6%
PARTICAL SIZE (US 100)	% Retained	NIL

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Rau Material Comparison - Digoxin USP (0111)

P.O.#	3929	3929-1
Test Type	Initial	Initial
Manufacturer	[redacted]	
Manufacturer Lot #		

PARAMETERS	SPECIFICATIONS	RESULTS	RESULTS
DESCRIPTION	Passes Test	Passes	Passes
IDENTIFICATION A	Positive	Passes	Passes
IDENTIFICATION B	Positive	Passes	Passes
IDENTIFICATION C	Positive	Passes	Passes
LOSS ON DRYING	NMT 1.0%	0.7%	0.5%
RESIDUE ON IGNITION	NMT 0.5%	0.1%	0.1%
RELATED GLYCOSIDES	NMT 3%	< 3%	< 3%
ASSAY	95.0 - 101.0%	98.6%	98.2%
BULK DENSITY		0.23 g/ml	0.21 g/ml
TAP DENSITY		0.36 g/ml	0.33 g/ml
PARTICLE SIZE (US 325)	% Retained	6.1%	6.8%
PARTICLE SIZE (US 200)	% Retained	Nil	Nil

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Comparison - Croscarmellose Sodium, NF (3000)

P.O. #	4026
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECEFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
IDENTIFICATION C	Positive	Passes
pH	5.0 - 7.0	6.5
LOSS ON DRYING	NMT 10.0%	2.5%
HEAVY METALS	NMT 0.001%	< 0.001%
SODIUM CHLORIDE & SODIUM STARCH GLYCOLATE	NMT 0.5%	0.21%
DEGREE OF SUBSTITUTION	0.60 to 0.85	0.69
CONTENT OF WATER SOLUBLE MATERIAL	1.0% - 10.0%	3.2%
SETTLING VOLUME	10.0 mL - 30.0 mL	22 mL
MICROBIAL TEST	Passes Test	Passes
BULK DENSITY		0.50 g/mL
TAP DENSITY		0.72 g/mL
PARTICLE SIZE (US 325)	% Retained	5.7%
PARTICLE SIZE (US 200)	% Retained	0.9%

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Comparison - Lactose Hydrous Impalpable NF (3051)

P.O. #	4028-1
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
CLARITY AND COLOR OF SOLUTION	Passes Test	Passes
LOSS ON DRYING	NMT 1.0%	0.3%
SPECIFIC ROTATION	+54.8° to +55.5°	+55.3°
MICROBIAL LIMITS	Passes Test	Passes
WATER	Hydrous: NMT 5.5%	5.1%
RESIDUE ON IGNITION	NMT 0.1%	0.03%
HEAVY METALS	NMT 5 ppm	< 5 ppm
ACIDITY/ALKALINITY	Passes Test	Passes
PROTEIN/LIGHT ABSORBING IMPUR.	Passes Test	Passes
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.58 g/mL
TAP DENSITY		0.87 g/mL
PARTICAL SIZE (US 200)	% Retained	83.7%
PARTICAL SIZE (US 325)	% Retained	11.3

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Comparison - Starch Pregelatinized NF (3088)

P.O. #	4027
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	4.5 - 7.0	5.9
IRON	NMT 0.002%	<0.002 %
OXIDIZING SUBSTANCES	Passes Test	Passes
SULFUR DIOXIDE	NMT: 0.008%	Passes
MICROBIAL LIMITS	Passes Test	Passes
LOSS ON DRYING	NMT 14.0%	8.8%
RESIDUE ON IGNITION	NMT 0.5%	0.2%
BULK DENSITY		0.66 g/mL
TAP DENSITY		0.84 g/mL
PARTICAL SIZE (US 100)	% Accumulation	2.7%
PARTICAL SIZE (US 200)	% Accumulation	26.6%
PARTICAL SIZE (US 325)	% Accumulation	51.5%

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Rau Material Comparison - Microcrystalline Cellulose, NF (3059)

P.O. #	4023
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	5.5 to 7.0	6.1
LOSS ON DRYING	NMT 5.0%	2.5%
RESIDUE ON IGNITION	NMT 0.05%	0.02%
WATER SOLUBLE SUBSTANCES	NMT 0.16%	0.10%
HEAVY METALS	NMT 0.001%	<0.001%
STARCH	Passes Test	Passes
ASSAY	97.0% - 102.0%	99.7%
BULK DENSITY		0.34 g/ml
TAP DENSITY		0.43 g/ml
PARTICAL SIZE (US 325)	% Retained	44.7%
PARTICAL SIZE (US 200)	% Retained	20.6%
PARTICAL SIZE (US 100)	% Retained	NIL

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Raw Material Comparison - Lactose Anhydrous, NF (DT) (3050)

P.O. #	4015
Test Type	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
CLARITY AND COLOR OF SOLUTION	Passes Test	Passes
LOSS ON DRYING	NMT 0.5%	0.2%
SPECIFIC ROTATION	Between +54.8° and +55.5°	+55.2°
MICROBIAL LIMITS	NMT 100 per gm	Passes
WATER	NMT 1.0%	0.4%
RESIDUE ON IGNITION	NMT 0.1%	0.04%
HEAVY METALS	NMT 5 ppm	< 5 ppm
ACIDITY/ALKALINITY	Passes Test	Passes
PROTEIN AND LIGHT ABSORBING IMPURITIES	NMT 0.25	Passes
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.57 g/m
TAP DENSITY		0.81 g/m
PARTICAL SIZE (US 100)	% Accumulation	13.1%
PARTICAL SIZE (US 200)	% Accumulation	28.6%
PARTICAL SIZE (US 325)	% Accumulation	40.5%

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Rau Material Comparison - Stearic Acid, NF (3089)

P.O.#	3910
Test Tupe	Initial
Manufacturer	[redacted]
Manufacturer Lot #	[redacted]

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
CONGEALING TEMPERATURE	NLT 54°	55°
RESIDUE ON IGNITION	NMT 0.1%	0.01
HEAVY METALS	NMT 0.001%	<0.001
MINERAL ACID	Passes Test	Passes
NEUTRAL FAT OR PARAFIN	Passes Test	Passes
IODINE VALUE	NMT 4	0.10
ASSAY A	NLT 40.0%	43.4%
ASSAY B	NLT 90.0%	96.4%
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.38 g/ml
TAP DENSITY		0.49 g/ml
PARTICAL SIZE (US 325)	% Retained	54.0%
PARTICAL SIZE (US 200)	% Retained	6.4%

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Rau Material Comparison - Silicon Dioxide, NF (3081)

P.O. #	3696
Test Tupe	[redacted]
Manufacturer	
Manufacturer Lot #	

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	4 - 8	6.7
LOSS ON DRYING	NMT 5.0%	4.0%
CHLORIDE	NMT 0.1%	<0.1%
SULFATE	NMT 0.5%	<0.5%
ARSENIC	NMT 3 ppm	<3 ppm
HEAVY METAL	NMT 0.003%	<0.003%
ASSAY	NLT 99.0%	99.6%
BULK DENSITY		0.10 g/ml
TAP DENSITY		0.13 g/ml
PARTICAL SIZE (US 325)	% Retained	Nil

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

PROTOCOL STEP - TEMPERATURE/HUMIDITY READINGS

Temperature and humidity readings will be taken in the production area. These three batches ran in production between 11/17/94 and 12/7/94.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

The temperature ranged from 62 - 87° F, and the relative humidity from 22 - 58%. This verifies that the product can be produced under normal plant conditions.

AMIDE PHARMACEUTICAL, INC.

TEMPERATURE/HUMIDITY READINGS

PERIOD COVERING DIGOXIN TABLETS, 0.25 mg

BATCH # 4330A, 4336A & 4337A

LOCATION	DATE	TEMP. (Deg. F)	RH (%)
Near Pr. Rm. #117	18-Nov-94	65	58
Near Pr. Rm. #117	19-Nov-94	71	58
Near Pr. Rm. #1	21-Nov-94	69	49
Near Pr. Rm. #117	22-Nov-94	73	39
Near Pr. Rm. #117	23-Nov-94	73	22
Near Pr. Rm. #117	25-Nov-94	66	31
Near Pr. Rm. #117	26-Nov-94	63	32
Near Pr. Rm. #1	28-Nov-94	64	49
Near Pr. Rm. #117	28-Nov-94	62	46
Near Pr. Rm. #1	29-Nov-94	66	38
Near Pr. Rm. #117	29-Nov-94	80	31
Near Pr. Rm. #117	30-Nov-94	75	32
Near Pr. Rm. #117	01-Dec-94	76	22
Near Pr. Rm. #117	02-Dec-94	64	37
Near Pr. Rm. #117	03-Dec-94	65	37
Near Pr. Rm. #117	05-Dec-94	78	49
Near Pr. Rm. #117	06-Dec-94	87	37
Near Pr. Rm. #117	07-Dec-94	74	46

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

STEP - BLEND UNIFORMITY

Sampling will include each of the three subparts produced in the 10 cu. ft. blender, and the final blend produced in the 56 cu. ft. double cone blender. Utilizing a sampling thief, sample each of the blenders from the positions shown on the attached data summary. Separately analyze, and report, each one for active ingredient content.

The speed of each blender will be monitored both empty and at each stage of blending.

ACCEPTANCE CRITERIA

Final Blend - 85.0 - 115.0 % Th. (Individual)

RESULTS - See the attached data summary.

CONCLUSIONS AND COMMENTS

The results show that each of the subparts were uniformly blended.The final blends for the three batches met all acceptance criteria and appear to be uniformly blended. Results are comparable to those obtained for the subparts.

The bulk and tamped density results are comparable for all three batches.

The speed for the three blenders was observed to be constant throughout production of the three batches. The same speed was obtained both empty and under load. The supporting documentation is attached.

3 Cu. Ft. (32) - 22 rpm
10 Cu. Ft. (35) - 16 rpm
56 Cu. Ft. (22) - 21 rpm

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

PRE BLEND - Assay (% Label)

Batch #	4330A	4330A	4330A	4336A	4336A	4336A	4337A	4337A	4337A
Part	1	2	3	1	2	3	1	2	3
Left Column - Top Left	100.0	102.2	100.2	97.6	100.7	97.8	99.5	100.2	100.6
Left Column - Top Center	99.3	99.6	98.7	98.6	99.9	98.7	98.8	101.0	102.6
Left Column - Top Right	99.3	100.4	99.4	99.2	99.8	100.7	100.2	101.1	101.5
Right Column - Top Left	100.3	101.0	102.6	99.3	98.7	99.5	100.8	98.3	101.2
Right Column - Top Center	99.2	101.5	102.0	99.5	98.9	100.3	100.8	98.5	100.4
Right Column - Top Right	100.8	101.8	101.8	98.7	98.1	100.8	100.5	102.4	101.0
Middle Left	100.4	103.6	102.5	98.9	101.2	99.4	100.9	102.0	101.6
Middle Center	101.4	102.1	100.5	100.2	98.4	100.6	101.6	102.6	101.8
Middle Right	101.8	101.8	98.7	99.1	101.3	99.8	101.7	101.9	102.8
Bottom Left	100.4	103.1	98.9	99.7	99.6	98.7	101.2	101.1	104.0
Bottom Right	100.3	101.9	101.0	99.7	99.3	100.5	98.8	102.4	102.3
Average	100.3	101.7	100.6	99.1	99.6	99.7	100.4	101.0	101.8
St Dev.	0.8	1.1	1.5	0.7	1.1	1.0	1.0	1.5	1.1
RSD	0.8	1.1	1.5	0.7	1.1	1.0	1.0	1.5	1.0

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

FINAL BLEND - Assay (% Label)

Batch #	4330A	4336A	4337A
Center - Top	100.3	100.6	101.1
Center - Middle	101.0	101.2	98.9
Center - Bottom	101.5	100.9	100.2
Left - Slope	100.7	100.1	103.8
Right - Slope	100.9	102.4	101.1
Left - Middle	99.4	103.0	102.9
Left - Top	101.0	102.4	102.5
Right - Middle	100.9	102.5	100.5
Right - Top	102.1	102.1	101.1
Front - Middle	102.0	100.0	100.9
Front - Top	99.9	100.9	102.0
Rear - Middle	102.2	100.5	101.3
Rear - Top	101.4	102.8	101.9
Average	101.0	101.5	101.4
St Dev.	0.8	1.1	1.3
RSD	0.8	1.1	1.2

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

FINAL BLEND - Density/Particle Size

Density (g/ml)

Batch #	4330A	4330A	4330A	4336A	4336A	4336A	4337A	4337A	4337A
Sample	Beginning	Middle	End	Beginning	Middle	End	Beginning	Middle	End
Bulk	0.61	0.61	0.61	0.60	0.60	0.60	0.60	0.60	0.60
Tap	0.90	0.90	0.90	0.85	0.85	0.85	0.85	0.85	0.85

Particle Size (% Retained)

Batch #	4330A	4330A	4330A	4336A	4336A	4336A	4337A	4337A	4337A
Mesh Size	Beginning	Middle	End	Beginning	Middle	End	Beginning	Middle	End
325	49.5	51.1	51.3	52.1	51.5	52.2	52.4	53	53.4
200	30.9	31.7	31.9	32.4	32.8	32.3	33.4	33.7	32.4
100	12.9	12.7	13.6	15	14.5	15.1	15.3	14.5	14.7
60	3.7	4.5	4.1	4.2	3.7	4.5	3.9	4.1	3.7
40	nil	nil	nil	nil	nil	nil	nil	nil	nil

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 1

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4330A MPR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL HEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
7:45Am	EMPTY.	0.00	22	KP	IP
	STEP #1.				
8:13Am	R.M. IP # 3115 + 0111 + 3000 *	16.31	22	KP	IP
	STEP # 2				
8:37Am	STEP #1 + 3051	41.30	22	KP	IP

PP2-046

Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 1

PRODUCT NAME (1): Digoxin Tablets 0.25mg (146)

BATCH #: 4330A MFR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
9:02 AM	EMPTY.	0.00	16	kb	IP
	STEP #1				
9:35 AM	R.M.ID# PRE BLEND + 3088 + 3059	111.30	16	kr	IP
	STEP #2				
10:25 AM	STEP #1 + 3050	163.10	16	kf	IP

PD2-066

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 9

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4330A HPR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
11:45Am	EMPTY.	0.00	22	KP	IP
	STEP #1.				
12:08Pm	R.M.ID # 3115 + 0111 + 3000	16.31	22	KP	IP
	STEP # 2				
12:25Pm	STEP #1 + 3051	41.30	22	KP	IP

PD2-066

Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 2

PRODUCT NAME (1): DIGOXIN TABLETS 0.25 mg (146)

BATCH #: 4330A HPR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
12:30pm	EMPTY.	0.00	16	KP	IP
	STEP #1				
1:08pm	PREBLEND + R.M.ID#3088+3059	111.30	16	KP	IP
	STEP #2				
1:26pm	STEP #1 + 3050	163.10	16	KP	IP

PD2-046

Amide Pharmaceutical, Inc.

PART # 3

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (1): DIGOXIN Tablets 0.25mg (141)

BATCH #: 4330A HPR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
2:32Pm	EMPTY.	0.00	22	KI	ZP
	STEP #1				
2:52Pm	R.M. ID # 3115+0111+3000	16.31	22	KI	ZP
	STEP # 2				
3:11Pm	STEP #1 + 3051	41.30	22	KI	ZP

FD2-066

harmaceutical, Inc.

PART # 3

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4330A HPR #: 14602 REV #: 00 DATE: 11/18/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
3:10Pm	EMPTY.	0.00	16	KP	IP
	~~PART~~ IP 11/18/94				
	STEP #1				
3:42Pm	PREBLEND + R.M. IP# 3088+3059	111.30	16	KP	IP
	STEP # 2				
4:02Pm	STEP #1 +3050	163.10	16	KP	IP

PD2-046

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4330A MPR #: 14602 REV #: 00 DATE: 11/21/94

BLENDER #: 22

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
9.35 Am	EMPTY	0.00	21.	K.P	J.D
10.22 Am	STEP #1		21	K.P	J.D
	PART# 1+2+3+3089+3081	504.0			

PD2-046

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 1

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 41336A HPR #: 14602 REV #: 00 DATE: 11/25/14

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
8:10 Am	Empty	0.00	22	KP	IP
8:42 Am	R.m. I)# STEP # 1 3115 + 0111 + 3000	16.31	22	KP	IP
	STEP # 2				
9:02 Am	STEP # 1 + 3051	41.30	22	KP	IP

PD2-048

...rmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 1

...JECT NAME (S): Digoxin Tablets 0.25 mg (146)

TCH #: 4336A HPR #: 14602 REV #: 00 DATE: 11/25/94

...ENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
9:15 Am	EMPTY.	0.00	16	KP	JP
	STEP #1				
9:56 Am	PRE BLEND + R.MGM 3058 + 3059	111.30	16	KP	JP
	STEP #2				
10:20 Am	STEP #1 + 3050	163.10	16	KP	JP

PD2-048

Amide Pharmaceutical, Inc.

PART # 2

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (1): Digoxin Tablets 0.25mg (146)

BATCH #: 4336A HPR #: 14602 REV #: 00 DATE: 11/25/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
11:01 Am	EMPTY.	0.00	22	KB	IP
	STEP #1				
11:59 Am	R.M. IP# 3115+0111+3000	16.31	22	KB	IP
	STEP #2				
12:16 Pm	STEP #1 + 3051	41.30	22	KB	IP

FD2-048

Pharmaceutical, Inc.

PART # 2

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (1): Digoxin Tablets 0.25 mg (146)

BATCH #: 41336A HPR #: 14602 REV #: 00 DATE: 11/25/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL HEIGHT (kg)	BLENDER'S RPM	DONE BY	CHECKED BY
11:05AM	EMPTY	0-00	16	KP	JP
	STEP #1				
12:50PM	PREBLEND + R-in-Fill A 3088+3059	111.30	16	KP	JP
	STEP #2				
1:13PM	STEP #1 + 3050	163.10	16	KP	JP

PD2-048

Amide Pharmaceutical, Inc.

PART # 3

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25 mg (146)

BATCH #: 4336A HPR #: 14602 REV #: 00 DATE: 11/25/04

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (kg)	BLENDER'S RPM	DONE BY	CHECKED BY
1:40 Pm	Empty	0.00	22	KP	IP
	Step #1				
2:08 Pm	R-M-ZP # 3115 + 0111 + 3000	16.31	22	KP	IP
	Step #2				
2:16 Pm	Step #1 + 3051	41.30	22	KP	IP

P02-068

Pharmaceutical, Inc.

PART #3

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4336A HPR #: 14602 REV #: 00 DATE: 11/25/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (kg)	BLENDER'S RPM	DONE BY	CHECKED BY
1:45pm	EMPTY.	0.00	16	kp	JP
	STEP #1				
2:45pm	PRELEND + A-M-F-N-A 3088 + 3059	111.30	16	kp	JP
	STEP #2				
3:10pm	STEP #1 + 3050	163.10	16	kp	JP

P02-046

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4336A HPR #: 14602 REV #: 00 DATE: 11/28/94

BLENDER #: 22

TIME	BLENDER'S CONTENTS	BLENDER'S TARG. MATERIAL WEIGHT (kg)	BLENDER'S RPM	DONE BY	CHECKED BY
7:40 AM	EMPTY.	0.00	21	G.C	IP
	STEP #1				
8:28 AM	R.M. ID # 3089 + 3081 + Part # 1,2,3	504.00	21	G.C	IP

FD2-028

Amide Pharmaceutical, Inc.

PART 1

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (1): Digoxin Tablets 0.25mg (146)

BATCH #: 4337A HPR #: 14602 REV #: 00 DATE: 11/26/74

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL HEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
12:35 Pm	EMPTY.	0.00	22	KI	JF
	STEP #1				
1:02 Pm	A.M.T.H. 3115 + 0111 + 3000	16.31	22	KI	JF
	STEP #2.				
1:19 Pm	STEP #1 + 3051	41.30	22	KI	JF

PD2-048

a Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

Part # 1

PRODUCT NAME (#): Digoxin Tablets 0.25 mg (146)

BATCH #: 4337A HPR #: 14602 REV #: 00 DATE: 11/26/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
1:40 Pm	EMPTY.	0.00	16	KP	JF
	STEP #1				
2:05 Pm	PREBLEND + RMID# 3088 + 3059	111.30	16	KP	JF
	STEP #2.				
2:37 Pm	STEP #1 + 3050	163.10	16	PV.	JF

PD2-048

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART #2

PRODUCT NAME (1): Digoxin Tablets 0.25mg (146)

BATCH #: 41337A HPR #: 14602 REV #: 00 DATE: 11/28/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
8:36Am	EMPTY.	0.00	22	KP	JP
	STEP #1				
8:53Am	R.M. ID # 3115 + 0111 + 3000	16.31	22	KP	JP
	STEP #2				
9:08Am	STEP #1 + 3051	41.30	22	KP	JP

PD2-068

harmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART #2

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4332A HPR #: 14602 REV #: 00 DATE: 11/28/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
9:30 AM	EMPTY	0.00	16	KP	JF
	STEP #1				
9:52 AM	PREBLEND + R.M. ID# 3088 + 3059	111.30	16	K.P	JF
	STEP #2				
10:25 ~~9:25~~ AM JF 11/28/94	STEP #1 + 3050	163.10	16	KP	JF

PD2-046

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PART # 3

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 4337A HPR #: 14602 REV #: 00 DATE: 11/28/94

BLENDER #: 32

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
12:05pm	EMPTY	0.00	22	KP	IP
	STEP # 1				
12:19pm	R.M. I.D. # 3115 + 0111 + 3000	16.31	22	KP	IP
	STEP # 2				
12:38pm	STEP # 1 + 3051	41.30	22	KP	IP

PD2-048

)6 Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET PART #3

PRODUCT NAME (#): Digoxin Tablets 0.25mg (146)

BATCH #: 41337A HPR #: 14602 REV #: 00 DATE: 11/28/94

BLENDER #: 35

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
12:58pm	EMPTY	0.00	16	KP	IP
	STEP #1				
1:25pm	R.M. #'S PREBLEND + 3088 + 3059	111.30	16	KP	IP
	STEP #2				
1:47pm	STEP #1 + 3050	163.10	16	KP	IP

PD2-046

Amide Pharmaceutical, Inc.

PROCESS VALIDATION DATA SHEET

PRODUCT NAME (#): Digoxin Tablets 0.25 mg (146)

BATCH #: 4337A HPR #: 14602 REV #: 00 DATE: 11/29/94

BLENDER #: 22

TIME	BLENDER'S CONTENTS	BLENDER'S THEO. MATERIAL WEIGHT (Kg)	BLENDER'S RPM	DONE BY	CHECKED BY
8:30 AM	EMPTY	0.00	21	[illegible]	[illegible]
	STEP #1				
9:13 AM	PART # 1+2+3+ R-M-FD # 3089+3081	504.00	21	[illegible]	[illegible]

PD2-016

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

PROTOCOL STEP - COMPRESSION

Samples were taken from each side of the press each 30 minutes and were evaluated for the following parameters.

Weight (n = 10)
Thickness (n = 5)
Hardness (n = 5)

These samples will be arranged chronologically and the batch divided into thirds. Front and rear will be analyzed separately as follows.

Friability	10 g - 1 run
Dissolution	N = 12 (6 front & 6 rear)
Disintegration	N = 6

Content uniformity is to be run across the entire batch. One tablet from each sample taken is to be run from the front, and one from the rear. A minimum of 30 is required from each side.

During compression a minimum quantity of tablets will be run at speeds higher and lower than normal. The actual speeds will be selected during production. These tablets will be evaluated for weight and hardness.

During compression minimum quantities of tablets will be run at hardness of 1.0 - 3 KP and greater than 8 KP. An attempt will also be made to run some tablets at the highest possible hardness that can be obtained without capping. These tablets will be evaluated for Dissolution and Friability.

ACCEPTANCE CRITERIA

Weight: 0.114 - 0.126 g
Hardness: 2.0 - 8.0 KP
Thickness: 2.7 - 3.7 mm
Friability: NMT 1.0 %
Dissolution: Meets USP Requirement
Disintegration: N/A (for characterization only)
Content Uniformity: 85.0 - 115.0 % TH, (RSD NMT 6.0 %)
Assay: 90.0 - 105.0 % Label

RESULTS - See attached data summary sheets.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

CONCLUSIONS AND COMMENTS

The samples met all acceptance criteria.

The values for weight, hardness, and thickness for the three batches were comparable to each other and showed no unusual shifts or trends. The overall averages for weight ,hardness and thickness are very close to the midpoints of the preset ranges. Therefore, no revisions to these limits are indicated by the validation data. Results are attached in both tabular and graphical form.

Content Uniformity was within limits for all samples tested, with no significant trends being observed. All values were within 96 - 106 % L. The values obtained were observed to agree favorably with the blend assays. It should be noted that the averages for the blend assays, and the content uniformity results are essentially the label amount.

All Dissolution samples for the three batches met the USP requirements. This statement is true for both USP XXII (60 Min.) and XXIII (15 & 60 Min.). The values for the three batches were comparable.

Friability values were all well within the acceptance criteria, and comparable for the three batches.

Disintegration results were comparable with no unusual shifts or trends. Note that this test was run for characterization only, and therefore no acceptance criteria have been, or will be, established.

Acceptable tablets were produced at the low and high press speed for all three batches. This establishes an allowable range of 18 - 28 rpm.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg MPR NO. 14602 - 00

BATCH	NORMAL	HIGH	LOW
4330A	22 rpm	26 rpm	18 rpm
4336A	23 rpm	27 rpm	19 rpm
4337A	24 rpm	28 rpm	19 rpm

The high and low hardness portion of the press validation produced acceptable tablets at both ends of the range. Tablets with hardness above the upper limit could not be produced. Therefore the guideline will remain at 2.0 - 8.0 KP. The values for friability are listed below. Those for dissolution are attached.

FRIABILITY (%)

BATCH		4330A	4336A	4337A
LOW KP	FRONT	0.1	0.2	0.2
	REAR	0.1	0.1	0.1
HIGH KP	FRONT	0.1	0.1	0.1
	REAR	0.1	0.1	0.2

The results for the overall composites are attached. These are also all within the acceptance criteria, and are essentially comparable to those obtained for the individual samples.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4330A

Compression Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/22/91	1:25 PM	0.119	0.120	0.119	0.118	0.121	0.119	0.120	0.120	0.120	0.121	0.120	0.001	0.8
11/22/91	2:10 PM	0.120	0.116	0.117	0.117	0.117	0.117	0.118	0.118	0.116	0.118	0.117	0.001	1.0
11/22/91	3:10 PM	0.118	0.121	0.117	0.118	0.118	0.119	0.118	0.118	0.119	0.119	0.119	0.001	0.9
11/23/91	8:10 AM	0.118	0.118	0.117	0.117	0.115	0.117	0.116	0.118	0.117	0.119	0.117	0.001	1.0
11/23/91	9:10 AM	0.117	0.117	0.116	0.117	0.118	0.118	0.118	0.117	0.115	0.117	0.117	0.001	0.8
11/23/91	10:10 AM	0.118	0.120	0.117	0.115	0.119	0.119	0.117	0.117	0.119	0.118	0.118	0.001	0.9
11/23/91	11:25 AM	0.119	0.119	0.119	0.117	0.119	0.119	0.120	0.119	0.118	0.119	0.119	0.001	0.7
11/23/91	12:25 PM	0.117	0.120	0.117	0.119	0.118	0.118	0.116	0.118	0.117	0.119	0.118	0.001	1.0
11/23/91	1:25 PM	0.118	0.119	0.119	0.121	0.118	0.118	0.119	0.120	0.118	0.120	0.119	0.001	0.9
11/23/91	2:35 PM	0.120	0.119	0.118	0.118	0.119	0.120	0.118	0.117	0.120	0.120	0.119	0.001	0.9
11/23/91	3:35 PM	0.118	0.120	0.119	0.120	0.118	0.119	0.119	0.117	0.117	0.118	0.119	0.001	0.9
11/25/91	7:35 AM	0.120	0.120	0.119	0.117	0.121	0.120	0.118	0.121	0.117	0.120	0.119	0.001	1.3
11/25/91	8:35 AM	0.121	0.119	0.120	0.120	0.119	0.118	0.119	0.120	0.120	0.119	0.120	0.001	0.7
11/25/91	9:10 AM	0.120	0.120	0.119	0.118	0.122	0.120	0.120	0.120	0.119	0.121	0.120	0.001	0.9
11/25/91	10:10 AM	0.121	0.120	0.118	0.119	0.118	0.119	0.118	0.122	0.119	0.120	0.119	0.001	1.1
11/25/91	11:10 AM	0.119	0.118	0.116	0.119	0.120	0.117	0.122	0.119	0.119	0.119	0.119	0.002	1.4
11/25/91	12:45 PM	0.116	0.120	0.121	0.120	0.117	0.119	0.119	0.119	0.119	0.120	0.119	0.001	1.3
11/25/91	1:15 PM	0.119	0.119	0.120	0.120	0.118	0.121	0.118	0.120	0.118	0.120	0.119	0.001	0.9
11/26/91	8:00 AM	0.118	0.119	0.120	0.120	0.121	0.118	0.121	0.120	0.120	0.121	0.120	0.001	0.9
11/26/91	9:00 AM	0.120	0.118	0.120	0.118	0.120	0.119	0.120	0.119	0.119	0.119	0.119	0.001	0.7
11/26/91	10:00 AM	0.118	0.121	0.119	0.118	0.118	0.119	0.119	0.118	0.120	0.119	0.119	0.001	0.8
11/26/91	11:10 AM	0.118	0.119	0.120	0.120	0.118	0.119	0.118	0.119	0.120	0.119	0.119	0.001	0.7
11/26/91	12:10 PM	0.119	0.118	0.120	0.119	0.118	0.120	0.120	0.118	0.121	0.120	0.119	0.001	0.9
11/26/91	1:10 PM	0.120	0.119	0.121	0.120	0.119	0.121	0.119	0.120	0.120	0.121	0.120	0.001	0.7
11/26/91	2:10 PM	0.118	0.120	0.119	0.119	0.118	0.119	0.119	0.119	0.120	0.118	0.119	0.001	0.7
11/28/91	8:05 AM	0.120	0.120	0.121	0.118	0.121	0.120	0.121	0.119	0.121	0.121	0.120	0.001	0.9
11/28/91	9:05 AM	0.119	0.120	0.118	0.120	0.120	0.116	0.120	0.116	0.121	0.119	0.119	0.002	1.5
11/28/91	10:05 AM	0.117	0.116	0.116	0.119	0.119	0.119	0.115	0.117	0.120	0.119	0.118	0.002	1.4
11/28/91	11:05 AM	0.121	0.118	0.119	0.119	0.119	0.121	0.120	0.119	0.120	0.119	0.120	0.001	0.8
11/28/91	12:10 PM	0.118	0.117	0.119	0.118	0.117	0.121	0.121	0.120	0.120	0.121	0.119	0.002	1.4
11/28/91	1:05 PM	0.119	0.120	0.121	0.119	0.120	0.119	0.120	0.118	0.122	0.119	0.120	0.001	1.0
11/28/91	2:05 PM	0.121	0.120	0.119	0.119	0.120	0.118	0.119	0.120	0.122	0.118	0.120	0.001	1.1
11/28/91	3:05 PM	0.118	0.116	0.122	0.121	0.117	0.122	0.119	0.120	0.121	0.117	0.119	0.002	1.9
11/28/91	4:05 PM	0.123	0.122	0.121	0.119	0.121	0.122	0.123	0.122	0.121	0.121	0.122	0.001	1.0
11/28/91	5:05 PM	0.119	0.118	0.117	0.118	0.119	0.116	0.118	0.117	0.117	0.117	0.118	0.001	0.8
11/29/91	10:25 AM	0.119	0.119	0.119	0.117	0.120	0.119	0.117	0.119	0.120	0.120	0.119	0.001	0.9

Compression Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/22/91	1:25 PM	0.119	0.120	0.118	0.119	0.119	0.118	0.120	0.119	0.118	0.119	0.119	0.001	0.7
11/22/91	2:10 PM	0.118	0.119	0.119	0.118	0.119	0.117	0.119	0.120	0.119	0.118	0.119	0.001	0.7
11/22/91	3:10 PM	0.121	0.120	0.121	0.119	0.120	0.121	0.120	0.120	0.121	0.121	0.120	0.001	0.6
11/23/91	8:10 AM	0.117	0.120	0.120	0.118	0.116	0.119	0.116	0.120	0.118	0.118	0.118	0.002	1.3
11/23/91	9:10 AM	0.111	0.119	0.117	0.117	0.119	0.117	0.117	0.116	0.119	0.119	0.117	0.002	1.4
11/23/91	10:10 AM	0.120	0.119	0.115	0.118	0.121	0.119	0.119	0.119	0.118	0.119	0.119	0.001	0.7
11/23/91	11:25 AM	0.120	0.119	0.118	0.119	0.119	0.118	0.119	0.117	0.121	0.121	0.119	0.001	1.1
11/23/91	12:25 PM	0.119	0.119	0.120	0.118	0.120	0.119	0.119	0.119	0.118	0.119	0.119	0.001	0.6
11/23/91	1:25 PM	0.121	0.120	0.120	0.121	0.119	0.120	0.121	0.120	0.121	0.121	0.120	0.001	0.6
11/23/91	2:35 PM	0.118	0.119	0.119	0.118	0.120	0.119	0.118	0.119	0.119	0.119	0.119	0.001	0.6
11/23/91	3:35 PM	0.118	0.119	0.119	0.119	0.118	0.121	0.120	0.119	0.117	0.121	0.119	0.001	1.2
11/25/91	7:35 AM	0.119	0.120	0.117	0.117	0.118	0.117	0.117	0.119	0.118	0.118	0.118	0.001	0.9
11/25/91	8:35 AM	0.118	0.119	0.121	0.117	0.119	0.118	0.117	0.118	0.116	0.119	0.118	0.001	1.2
11/25/91	9:10 AM	0.119	0.120	0.120	0.119	0.119	0.119	0.118	0.117	0.119	0.117	0.119	0.001	0.9
11/25/91	10:10 AM	0.121	0.121	0.118	0.119	0.118	0.120	0.119	0.119	0.122	0.119	0.120	0.001	1.2
11/25/91	11:10 AM	0.118	0.118	0.120	0.117	0.118	0.118	0.120	0.118	0.121	0.118	0.119	0.001	1.1
11/25/91	12:45 PM	0.120	0.120	0.119	0.120	0.120	0.119	0.118	0.119	0.119	0.120	0.119	0.001	0.6
11/25/91	1:15 PM	0.118	0.118	0.120	0.120	0.118	0.120	0.119	0.118	0.118	0.119	0.119	0.001	0.8
11/26/91	8:00 AM	0.119	0.118	0.121	0.120	0.118	0.119	0.120	0.118	0.119	0.120	0.119	0.001	0.9
11/26/91	9:00 AM	0.121	0.118	0.120	0.119	0.120	0.121	0.119	0.119	0.120	0.121	0.120	0.001	0.9
11/26/91	10:00 AM	0.120	0.118	0.119	0.120	0.118	0.121	0.120	0.118	0.121	0.119	0.119	0.001	1.0
11/26/91	11:10 AM	0.119	0.120	0.119	0.119	0.120	0.121	0.119	0.120	0.120	0.118	0.120	0.001	0.7
11/26/91	12:10 PM	0.120	0.120	0.119	0.120	0.121	0.121	0.119	0.121	0.119	0.121	0.120	0.001	0.7
11/26/91	1:10 PM	0.120	0.119	0.119	0.121	0.118	0.120	0.119	0.122	0.119	0.120	0.120	0.001	1.0
11/26/91	2:10 PM	0.120	0.120	0.119	0.121	0.118	0.119	0.121	0.118	0.120	0.121	0.120	0.001	1.0
11/28/91	8:05 AM	0.120	0.120	0.121	0.120	0.118	0.120	0.118	0.119	0.119	0.119	0.119	0.001	0.8
11/28/91	9:05 AM	0.119	0.118	0.119	0.117	0.118	0.116	0.119	0.118	0.117	0.118	0.118	0.001	0.8
11/28/91	10:05 AM	0.117	0.117	0.118	0.116	0.119	0.118	0.119	0.116	0.118	0.119	0.118	0.001	1.0
11/28/91	11:05 AM	0.116	0.117	0.117	0.118	0.118	0.119	0.117	0.119	0.119	0.119	0.118	0.001	0.9
11/28/91	12:10 PM	0.118	0.117	0.120	0.116	0.117	0.119	0.119	0.119	0.117	0.120	0.118	0.001	1.1
11/28/91	1:05 PM	0.116	0.117	0.117	0.119	0.118	0.118	0.117	0.119	0.119	0.119	0.118	0.001	0.8
11/28/91	2:05 PM	0.119	0.119	0.120	0.117	0.119	0.117	0.122	0.121	0.119	0.119	0.119	0.002	1.3
11/28/91	3:05 PM	0.119	0.116	0.118	0.122	0.120	0.116	0.117	0.119	0.119	0.118	0.118	0.002	1.5
11/28/91	4:05 PM	0.117	0.119	0.118	0.120	0.119	0.119	0.119	0.119	0.120	0.119	0.119	0.001	0.8
11/28/91	5:05 PM	0.121	0.121	0.120	0.120	0.121	0.121	0.120	0.120	0.120	0.119	0.120	0.001	0.6
11/29/91	10:25 AM	0.120	0.122	0.119	0.120	0.122	0.119	0.120	0.121	0.119	0.121	0.120	0.001	1.0

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4336A

Compression Height (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/29/94	2:45 PM	0.120	0.121	0.122	0.122	0.120	0.121	0.121	0.121	0.119	0.121	0.121	0.001	0.8
11/29/94	3:45 PM	0.122	0.121	0.121	0.119	0.120	0.121	0.120	0.121	0.122	0.120	0.121	0.001	0.8
11/29/94	4:45 PM	0.120	0.120	0.119	0.120	0.120	0.121	0.122	0.121	0.121	0.123	0.121	0.001	1.0
11/29/94	5:45 PM	0.120	0.123	0.121	0.123	0.122	0.122	0.122	0.122	0.121	0.120	0.122	0.001	0.9
11/29/94	6:45 PM	0.121	0.119	0.119	0.120	0.120	0.119	0.120	0.122	0.121	0.120	0.120	0.001	0.8
11/29/94	7:55 PM	0.119	0.120	0.119	0.118	0.118	0.119	0.121	0.120	0.119	0.118	0.119	0.001	0.8
11/29/94	8:55 AM	0.119	0.121	0.121	0.117	0.120	0.119	0.122	0.118	0.119	0.121	0.120	0.002	1.3
11/30/94	8:00 AM	0.121	0.122	0.121	0.121	0.120	0.119	0.119	0.121	0.121	0.121	0.121	0.001	0.8
11/30/94	9:00 AM	0.120	0.123	0.120	0.123	0.124	0.122	0.121	0.120	0.120	0.120	0.121	0.002	1.3
11/30/94	10:00 AM	0.120	0.121	0.120	0.119	0.119	0.121	0.119	0.119	0.118	0.122	0.120	0.001	1.0
11/30/94	11:00 AM	0.120	0.121	0.121	0.121	0.121	0.119	0.120	0.121	0.119	0.120	0.120	0.001	0.7
11/30/94	12:00 PM	0.120	0.122	0.120	0.123	0.121	0.122	0.121	0.120	0.122	0.120	0.121	0.001	0.9
11/30/94	1:00 PM	0.118	0.118	0.119	0.119	0.120	0.117	0.118	0.120	0.119	0.118	0.119	0.001	0.8
11/30/94	2:00 PM	0.118	0.119	0.121	0.119	0.121	0.122	0.119	0.120	0.120	0.119	0.120	0.001	1.0
11/30/94	3:00 PM	0.119	0.120	0.118	0.119	0.120	0.120	0.119	0.121	0.119	0.119	0.119	0.001	0.7
11/30/94	4:00 PM	0.120	0.121	0.119	0.119	0.119	0.120	0.119	0.121	0.119	0.118	0.120	0.001	0.8
11/30/94	5:00 PM	0.120	0.118	0.119	0.119	0.120	0.119	0.120	0.121	0.119	0.118	0.119	0.001	0.8
11/30/94	6:00 PM	0.118	0.119	0.119	0.120	0.120	0.120	0.119	0.121	0.120	0.119	0.120	0.001	0.7
11/30/94	7:00 PM	0.122	0.118	0.122	0.120	0.118	0.122	0.120	0.119	0.119	0.119	0.120	0.002	1.4
11/30/94	8:00 PM	0.121	0.119	0.119	0.120	0.121	0.118	0.120	0.119	0.119	0.120	0.120	0.001	0.8
11/30/94	9:00 PM	0.118	0.121	0.120	0.121	0.118	0.120	0.119	0.120	0.121	0.120	0.120	0.001	0.9
12/1/94	7:50 AM	0.120	0.119	0.120	0.119	0.121	0.120	0.121	0.119	0.120	0.121	0.120	0.001	0.7
12/1/94	8:50 AM	0.120	0.123	0.118	0.120	0.121	0.120	0.121	0.119	0.120	0.121	0.120	0.001	1.1
12/1/94	9:50 AM	0.119	0.121	0.120	0.118	0.119	0.119	0.121	0.121	0.120	0.119	0.120	0.001	0.9
12/1/94	10:50 AM	0.117	0.122	0.119	0.120	0.118	0.118	0.120	0.120	0.120	0.117	0.119	0.002	1.3
12/1/94	11:50 AM	0.121	0.120	0.120	0.120	0.116	0.119	0.119	0.121	0.118	0.120	0.119	0.002	1.3
12/1/94	12:50 PM	0.121	0.122	0.120	0.117	0.122	0.119	0.123	0.120	0.122	0.121	0.121	0.002	1.6
12/1/94	1:45 PM	0.120	0.117	0.117	0.119	0.120	0.119	0.120	0.119	0.119	0.119	0.119	0.001	0.9
12/1/94	2:45 PM	0.118	0.116	0.119	0.118	0.118	0.119	0.118	0.118	0.118	0.120	0.118	0.001	0.9
12/1/94	4:10 PM	0.119	0.119	0.121	0.121	0.119	0.120	0.121	0.122	0.119	0.120	0.120	0.001	0.9
12/1/94	5:10 PM	0.121	0.120	0.120	0.122	0.120	0.121	0.120	0.119	0.123	0.119	0.121	0.001	1.1
12/1/94	6:10 PM	0.120	0.123	0.122	0.120	0.120	0.121	0.120	0.121	0.122	0.121	0.121	0.001	0.9
12/1/94	7:25 PM	0.119	0.118	0.120	0.120	0.121	0.123	0.120	0.121	0.119	0.120	0.120	0.001	1.1
12/1/94	8:25 PM	0.123	0.122	0.120	0.121	0.123	0.120	0.122	0.122	0.122	0.120	0.122	0.001	1.0
12/1/94	9:25 PM	0.121	0.122	0.120	0.119	0.120	0.121	0.120	0.120	0.122	0.121	0.121	0.001	0.8

Compression Height (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/29/94	2:45 PM	0.119	0.120	0.121	0.117	0.119	0.121	0.122	0.120	0.120	0.120	0.120	0.001	1.1
11/29/94	3:45 PM	0.120	0.120	0.121	0.120	0.120	0.123	0.121	0.122	0.122	0.121	0.121	0.001	0.9
11/29/94	4:45 PM	0.122	0.121	0.121	0.122	0.121	0.122	0.119	0.120	0.123	0.122	0.121	0.001	1.0
11/29/94	5:45 PM	0.121	0.122	0.124	0.122	0.123	0.122	0.123	0.120	0.121	0.123	0.122	0.001	1.0
11/29/94	6:45 PM	0.120	0.118	0.119	0.118	0.119	0.120	0.118	0.118	0.121	0.118	0.119	0.001	0.9
11/29/94	7:55 PM	0.120	0.121	0.119	0.119	0.122	0.119	0.120	0.121	0.121	0.121	0.120	0.001	0.9
11/29/94	8:55 AM	0.123	0.119	0.121	0.120	0.118	0.120	0.119	0.123	0.119	0.119	0.120	0.002	1.6
11/30/94	8:00 AM	0.120	0.121	0.120	0.120	0.123	0.121	0.122	0.120	0.118	0.122	0.121	0.001	1.2
11/30/94	9:00 AM	0.120	0.122	0.120	0.119	0.122	0.123	0.120	0.121	0.123	0.120	0.121	0.001	1.2
11/30/94	10:00 AM	0.119	0.118	0.121	0.119	0.121	0.118	0.119	0.120	0.122	0.122	0.120	0.002	1.3
11/30/94	11:00 AM	0.118	0.119	0.119	0.119	0.120	0.120	0.119	0.120	0.119	0.120	0.119	0.001	0.6
11/30/94	12:00 PM	0.119	0.119	0.120	0.120	0.121	0.119	0.120	0.123	0.119	0.119	0.120	0.001	1.1
11/30/94	1:00 PM	0.120	0.120	0.120	0.118	0.119	0.118	0.118	0.119	0.120	0.120	0.119	0.001	0.8
11/30/94	2:00 PM	0.120	0.119	0.118	0.120	0.119	0.119	0.118	0.121	0.121	0.119	0.119	0.001	0.9
11/30/94	3:00 PM	0.120	0.120	0.120	0.121	0.118	0.119	0.121	0.122	0.118	0.120	0.120	0.001	1.1
11/30/94	4:00 PM	0.119	0.118	0.118	0.119	0.120	0.119	0.118	0.118	0.120	0.118	0.119	0.001	0.7
11/30/94	5:00 PM	0.120	0.119	0.121	0.118	0.121	0.119	0.118	0.118	0.119	0.118	0.119	0.001	1.0
11/30/94	6:00 PM	0.121	0.120	0.119	0.119	0.121	0.119	0.120	0.119	0.121	0.119	0.120	0.001	0.8
11/30/94	7:00 PM	0.118	0.119	0.120	0.120	0.121	0.118	0.118	0.118	0.120	0.119	0.119	0.001	0.9
11/30/94	8:00 PM	0.119	0.120	0.118	0.119	0.118	0.121	0.118	0.118	0.119	0.120	0.119	0.001	0.9
11/30/94	9:00 PM	0.118	0.119	0.119	0.121	0.119	0.121	0.119	0.119	0.121	0.120	0.120	0.001	0.9
12/1/94	7:50 AM	0.121	0.124	0.121	0.120	0.121	0.122	0.122	0.120	0.122	0.120	0.121	0.001	1.0
12/1/94	8:50 AM	0.121	0.121	0.119	0.119	0.119	0.120	0.118	0.119	0.120	0.120	0.120	0.001	0.8
12/1/94	9:50 AM	0.116	0.119	0.122	0.120	0.116	0.120	0.121	0.117	0.117	0.119	0.119	0.002	1.8
12/1/94	10:50 AM	0.120	0.119	0.118	0.120	0.119	0.118	0.120	0.120	0.118	0.120	0.119	0.001	0.8
12/1/94	11:50 AM	0.119	0.119	0.119	0.121	0.121	0.119	0.120	0.118	0.122	0.119	0.120	0.001	1.1
12/1/94	12:50 PM	0.120	0.121	0.117	0.121	0.121	0.123	0.119	0.123	0.122	0.119	0.121	0.002	1.6
12/1/94	1:45 PM	0.120	0.119	0.118	0.117	0.121	0.120	0.119	0.119	0.120	0.122	0.119	0.002	1.3
12/1/94	2:45 PM	0.121	0.120	0.124	0.119	0.118	0.122	0.117	0.122	0.121	0.120	0.120	0.002	1.7
12/1/94	4:10 PM	0.120	0.119	0.120	0.122	0.121	0.119	0.119	0.120	0.121	0.120	0.120	0.001	0.8
12/1/94	5:10 PM	0.118	0.121	0.119	0.120	0.120	0.120	0.119	0.119	0.120	0.121	0.120	0.001	0.8
12/1/94	6:10 PM	0.120	0.122	0.120	0.122	0.122	0.119	0.118	0.119	0.119	0.120	0.120	0.001	1.2
12/1/94	7:25 PM	0.120	0.119	0.120	0.116	0.117	0.121	0.120	0.121	0.120	0.120	0.119	0.002	1.4
12/1/94	8:25 PM	0.120	0.121	0.120	0.120	0.120	0.121	0.120	0.120	0.122	0.117	0.120	0.001	1.1
12/1/94	9:25 PM	0.121	0.120	0.120	0.119	0.119	0.120	0.118	0.120	0.121	0.120	0.120	0.001	0.8

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

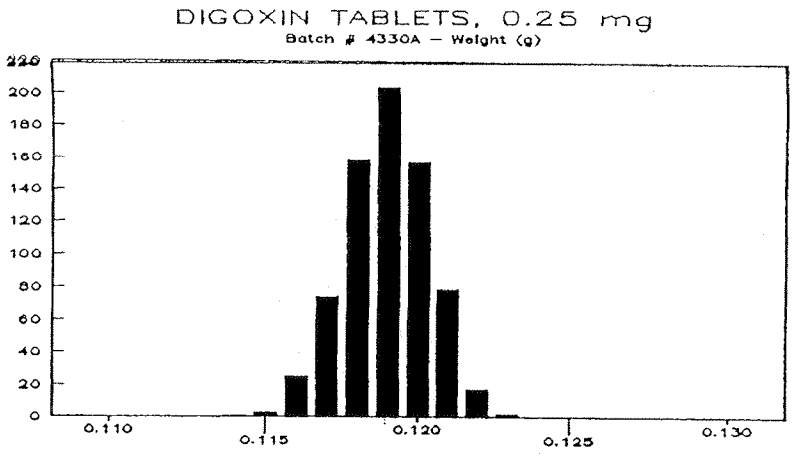
DIGOXIN TABLETS, 0.25 mg - Batch # 4337A

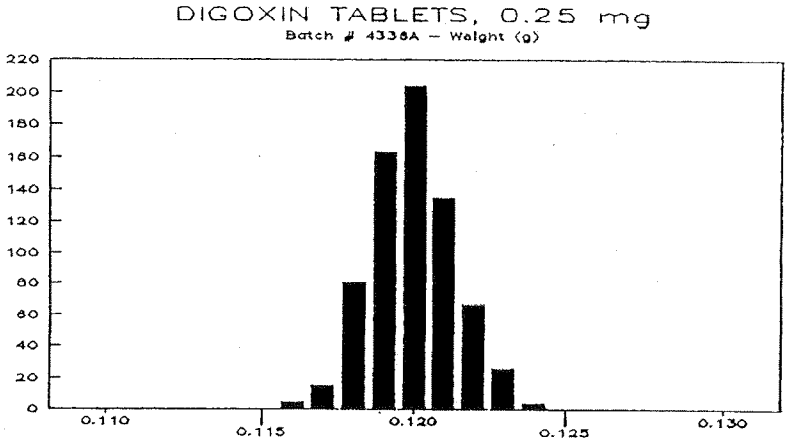
Compression Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
12/2/91	10:00 AM	0.121	0.120	0.120	0.119	0.120	0.122	0.121	0.120	0.119	0.120	0.120	0.001	0.9
12/2/91	11:00 AM	0.118	0.119	0.121	0.120	0.119	0.120	0.120	0.119	0.119	0.120	0.120	0.001	0.7
12/2/91	12:00 PM	0.117	0.117	0.115	0.119	0.115	0.115	0.116	0.116	0.118	0.117	0.117	0.001	1.2
12/2/91	1:00 PM	0.120	0.120	0.121	0.121	0.123	0.122	0.122	0.122	0.120	0.121	0.121	0.001	0.9
12/2/91	1:25 PM	0.119	0.120	0.125	0.120	0.120	0.119	0.119	0.120	0.121	0.120	0.120	0.002	1.6
12/2/91	2:05 PM	0.118	0.119	0.119	0.119	0.118	0.120	0.119	0.120	0.121	0.120	0.119	0.001	0.8
12/2/91	3:40 PM	0.116	0.119	0.116	0.115	0.116	0.114	0.115	0.115	0.114	0.116	0.115	0.001	0.9
12/2/91	3:40 PM	0.110	0.117	0.115	0.119	0.116	0.114	0.119	0.114	0.115	0.114	0.115	0.002	2.1
12/3/91	7:20 AM	0.119	0.119	0.120	0.120	0.120	0.121	0.121	0.119	0.120	0.121	0.120	0.001	0.7
12/3/91	8:20 AM	0.120	0.119	0.121	0.119	0.122	0.119	0.121	0.121	0.118	0.118	0.120	0.001	1.2
12/3/91	9:20 AM	0.118	0.120	0.119	0.120	0.119	0.118	0.119	0.120	0.121	0.118	0.119	0.001	0.9
12/3/91	10:20 AM	0.119	0.120	0.122	0.119	0.120	0.119	0.120	0.121	0.119	0.119	0.120	0.001	0.9
12/3/91	11:35 AM	0.120	0.121	0.120	0.120	0.121	0.121	0.122	0.120	0.120	0.120	0.121	0.001	0.6
12/3/91	12:35 PM	0.119	0.120	0.121	0.122	0.121	0.122	0.120	0.118	0.120	0.122	0.121	0.001	1.1
12/3/91	1:35 PM	0.122	0.121	0.123	0.121	0.122	0.122	0.120	0.121	0.121	0.122	0.122	0.001	0.7
12/3/91	2:35 PM	0.120	0.120	0.122	0.121	0.120	0.117	0.121	0.120	0.119	0.121	0.120	0.001	1.1
12/5/91	7:55 AM	0.119	0.120	0.120	0.121	0.120	0.119	0.119	0.119	0.122	0.120	0.120	0.001	0.8
12/5/91	8:55 AM	0.120	0.121	0.120	0.122	0.120	0.120	0.120	0.119	0.121	0.122	0.121	0.001	0.8
12/5/91	9:55 AM	0.123	0.120	0.123	0.119	0.119	0.120	0.122	0.120	0.122	0.120	0.121	0.002	1.9
12/5/91	10:50 AM	0.118	0.118	0.120	0.118	0.119	0.121	0.118	0.119	0.119	0.120	0.119	0.001	0.8
12/5/91	11:50 AM	0.122	0.119	0.120	0.121	0.120	0.120	0.121	0.122	0.120	0.121	0.121	0.001	0.8
12/5/91	12:50 PM	0.120	0.120	0.121	0.120	0.122	0.120	0.121	0.118	0.121	0.120	0.120	0.001	0.9
12/5/91	1:50 PM	0.121	0.122	0.122	0.121	0.123	0.121	0.121	0.121	0.121	0.121	0.121	0.001	0.6
12/5/91	2:50 PM	0.120	0.121	0.121	0.119	0.120	0.121	0.118	0.121	0.119	0.119	0.120	0.001	0.9
12/5/91	3:50 PM	0.119	0.120	0.119	0.120	0.120	0.120	0.121	0.121	0.119	0.119	0.120	0.001	0.7
12/5/91	4:50 PM	0.119	0.118	0.120	0.119	0.120	0.121	0.120	0.119	0.120	0.120	0.120	0.001	0.7
12/5/91	5:90 PM	0.120	0.119	0.119	0.118	0.120	0.119	0.120	0.120	0.118	0.119	0.119	0.001	0.7
12/6/91	7:50 AM	0.120	0.120	0.120	0.119	0.119	0.120	0.119	0.118	0.121	0.119	0.120	0.001	0.7
12/6/91	9:35 AM	0.122	0.121	0.119	0.121	0.117	0.120	0.121	0.119	0.119	0.121	0.120	0.001	1.2
12/6/91	10:35 AM	0.119	0.120	0.121	0.121	0.120	0.118	0.120	0.121	0.119	0.120	0.120	0.001	0.9
12/6/91	11:35 AM	0.120	0.122	0.120	0.121	0.120	0.120	0.121	0.119	0.120	0.121	0.120	0.001	0.7
12/6/91	12:35 PM	0.122	0.121	0.122	0.120	0.122	0.121	0.120	0.121	0.120	0.121	0.121	0.001	0.7
12/6/91	1:40 PM	0.122	0.120	0.121	0.118	0.121	0.120	0.120	0.122	0.121	0.120	0.121	0.001	1.0
12/6/91	2:40 PM	0.121	0.121	0.118	0.122	0.118	0.118	0.122	0.117	0.122	0.120	0.120	0.002	1.6
12/6/91	3:35 PM	0.121	0.120	0.121	0.118	0.121	0.120	0.120	0.121	0.119	0.119	0.120	0.001	0.9
12/7/91	7:50 AM	0.122	0.121	0.121	0.122	0.122	0.122	0.121	0.121	0.121	0.123	0.122	0.001	0.6
12/7/91	8:50 AM	0.119	0.120	0.120	0.120	0.118	0.121	0.121	0.120	0.120	0.120	0.120	0.001	0.7
12/7/91	9:50 AM	0.121	0.119	0.122	0.121	0.118	0.119	0.121	0.121	0.119	0.119	0.120	0.002	1.6
12/7/91	11:35 AM	0.118	0.118	0.118	0.119	0.118	0.117	0.119	0.117	0.115	0.120	0.118	0.001	1.2

Compression Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
12/2/91	10:00 AM	0.118	0.117	0.119	0.119	0.119	0.120	0.118	0.119	0.120	0.118	0.119	0.001	0.8
12/2/91	11:00 AM	0.118	0.119	0.119	0.120	0.119	0.121	0.118	0.118	0.120	0.121	0.119	0.001	1.0
12/2/91	12:00 PM	0.118	0.115	0.118	0.118	0.117	0.119	0.119	0.118	0.117	0.116	0.118	0.001	1.1
12/2/91	1:00 PM	0.124	0.129	0.124	0.120	0.124	0.121	0.123	0.125	0.122	0.122	0.123	0.002	2.0
12/2/91	1:00 PM	0.121	0.120	0.122	0.123	0.122	0.125	0.121	0.125	0.122	0.126	0.123	0.002	1.6
12/2/91	1:25 PM	0.121	0.120	0.122	0.120	0.121	0.121	0.120	0.120	0.119	0.122	0.121	0.001	0.8
12/2/91	2:05 PM	0.121	0.121	0.119	0.121	0.121	0.120	0.122	0.118	0.118	0.118	0.120	0.002	1.9
12/2/91	3:40 PM	0.116	0.120	0.111	0.119	0.111	0.115	0.116	0.117	0.114	0.115	0.116	0.002	1.8
12/3/91	7:20 AM	0.119	0.122	0.123	0.121	0.120	0.120	0.118	0.123	0.122	0.120	0.121	0.002	1.5
12/3/91	8:20 AM	0.120	0.123	0.121	0.122	0.124	0.120	0.121	0.119	0.120	0.122	0.121	0.002	1.9
12/3/91	9:20 AM	0.120	0.122	0.120	0.120	0.121	0.120	0.123	0.119	0.123	0.120	0.121	0.001	1.2
12/3/91	10:20 AM	0.123	0.118	0.121	0.123	0.120	0.119	0.122	0.120	0.121	0.120	0.121	0.002	1.4
12/3/91	11:35 AM	0.120	0.119	0.123	0.119	0.119	0.119	0.122	0.122	0.120	0.119	0.120	0.002	1.9
12/3/91	12:35 PM	0.119	0.120	0.121	0.121	0.121	0.123	0.122	0.120	0.123	0.118	0.121	0.001	1.2
12/3/91	1:35 PM	0.119	0.121	0.120	0.120	0.120	0.121	0.122	0.119	0.119	0.120	0.120	0.001	1.0
12/3/91	2:35 PM	0.121	0.119	0.121	0.120	0.120	0.120	0.119	0.120	0.120	0.119	0.120	0.001	0.6
12/5/91	7:55 AM	0.120	0.119	0.122	0.121	0.123	0.120	0.121	0.119	0.120	0.117	0.120	0.002	1.4
12/5/91	8:55 AM	0.122	0.122	0.120	0.121	0.120	0.120	0.121	0.121	0.122	0.120	0.121	0.001	0.7
12/5/91	9:55 AM	0.121	0.120	0.120	0.117	0.119	0.120	0.120	0.119	0.119	0.120	0.120	0.001	0.9
12/5/91	11:00 AM	0.121	0.121	0.120	0.119	0.121	0.120	0.120	0.120	0.119	0.120	0.120	0.001	0.6
12/5/91	11:50 AM	0.119	0.121	0.120	0.120	0.120	0.122	0.120	0.121	0.121	0.121	0.121	0.001	0.7
12/5/91	12:50 PM	0.122	0.120	0.122	0.121	0.120	0.118	0.121	0.120	0.121	0.120	0.121	0.001	1.0
12/5/91	1:50 PM	0.121	0.120	0.121	0.121	0.119	0.121	0.119	0.121	0.121	0.118	0.120	0.001	0.9
12/5/91	2:50 PM	0.120	0.120	0.121	0.120	0.121	0.121	0.121	0.121	0.119	0.121	0.121	0.001	0.6
12/5/91	3:50 PM	0.120	0.121	0.117	0.120	0.120	0.121	0.123	0.121	0.122	0.121	0.121	0.002	1.9
12/5/91	4:50 PM	0.121	0.121	0.120	0.120	0.120	0.123	0.120	0.121	0.121	0.121	0.121	0.001	0.8
12/5/91	5:30 PM	0.120	0.117	0.120	0.119	0.120	0.120	0.120	0.120	0.120	0.120	0.120	0.001	0.9
12/6/91	7:50 AM	0.122	0.120	0.121	0.120	0.121	0.120	0.120	0.121	0.120	0.121	0.121	0.001	0.6
12/6/91	9:35 AM	0.119	0.120	0.119	0.120	0.120	0.118	0.120	0.120	0.121	0.120	0.119	0.001	0.9
12/6/91	10:35 AM	0.118	0.118	0.120	0.121	0.120	0.119	0.119	0.120	0.117	0.120	0.119	0.001	0.9
12/6/91	11:35 AM	0.121	0.120	0.118	0.119	0.121	0.118	0.119	0.120	0.119	0.118	0.119	0.001	1.0
12/6/91	12:35 PM	0.122	0.123	0.119	0.121	0.120	0.119	0.119	0.123	0.117	0.120	0.120	0.002	1.6
12/6/91	1:40 PM	0.119	0.121	0.120	0.121	0.122	0.121	0.119	0.121	0.120	0.123	0.121	0.001	1.0
12/6/91	2:40 PM	0.120	0.121	0.119	0.121	0.121	0.121	0.118	0.120	0.121	0.118	0.120	0.001	1.0
12/6/91	3:35 PM	0.122	0.121	0.120	0.121	0.118	0.121	0.121	0.123	0.119	0.118	0.121	0.002	1.7
12/7/91	7:50 AM	0.119	0.122	0.120	0.121	0.121	0.121	0.120	0.121	0.121	0.119	0.121	0.001	0.8
12/7/91	8:50 AM	0.120	0.121	0.120	0.120	0.121	0.120	0.121	0.121	0.119	0.118	0.120	0.001	0.8
12/7/91	9:50 AM	0.117	0.121	0.119	0.120	0.120	0.119	0.119	0.119	0.121	0.119	0.119	0.001	1.0
12/7/91	11:35 AM	0.122	0.117	0.119	0.119	0.123	0.121	0.120	0.120	0.120	0.119	0.120	0.002	1.4


DIGOXIN TABLETS, 0.25 mg
Batch # 4330A – Weight (g)
220
200
180
160
140
120
100
80
60
40
20
0
0.110
0.115
0.120
0.125
0.130


DIGOXIN TABLETS, 0.25 mg
Batch # 4336A – Weight (g)
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200
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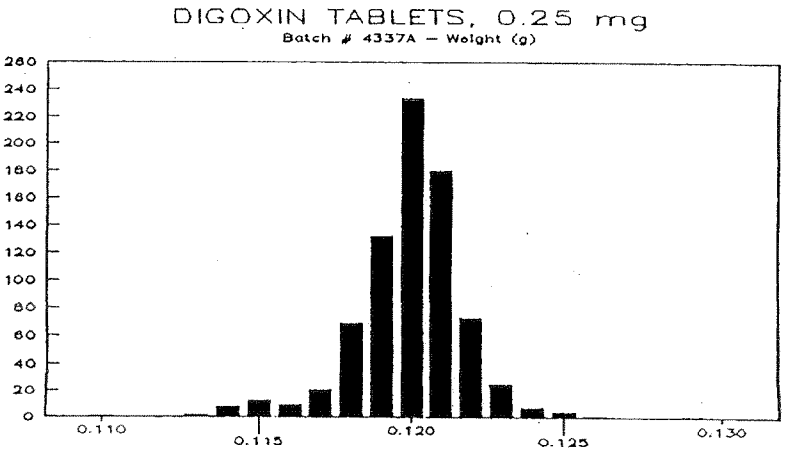
160
140
120
100
80
60
40
20
0
0.110
0.115
0.120
0.125
0.130


DIGOXIN TABLETS, 0.25 mg
Batch # 4337A – Weight (g)
260
240
220
200
180
160
140
120
100
80
60
40
20
0
0.110
0.115
0.120
0.125
0.130

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4330A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/22/91	1:25 PM	5.3	5.7	5.9	5.1	6.7	5.6	0.2	4.1
11/22/91	2:40 PM	4.7	5.1	4.3	4.9	5.0	4.8	0.3	6.6
11/22/91	3:40 PM	4.6	5.0	5.1	4.8	4.8	4.9	0.2	4.0
11/23/91	8:10 AM	4.7	5.1	4.7	5.0	4.4	4.8	0.3	5.8
11/23/91	9:10 AM	4.8	5.3	4.8	4.4	4.9	4.8	0.3	6.6
11/23/91	10:10 AM	5.0	5.0	5.6	5.3	5.0	5.2	0.3	5.2
11/23/91	11:25 AM	5.4	5.4	5.2	5.1	4.9	5.2	0.2	4.1
11/23/91	12:25 PM	4.4	5.7	5.7	5.3	5.4	5.3	0.5	10.1
11/23/91	1:25 PM	5.1	5.3	5.1	5.5	5.5	5.3	0.2	3.8
11/23/91	2:35 PM	5.8	5.4	5.2	4.9	5.4	5.5	0.4	6.5
11/23/91	3:35 PM	5.0	5.1	5.5	5.4	5.1	5.2	0.2	4.2
11/25/91	7:35 AM	5.1	4.5	4.3	4.5	4.9	4.7	0.3	7.1
11/25/91	8:35 AM	5.3	4.6	5.4	5.1	5.2	5.2	0.5	9.0
11/25/91	9:40 AM	4.7	5.0	5.4	4.7	5.3	5.0	0.3	6.8
11/25/91	10:40 AM	5.3	4.9	4.6	4.0	4.9	5.1	0.6	11.1
11/25/91	11:40 AM	4.7	5.3	5.3	5.0	5.4	5.2	0.3	6.6
11/25/91	12:45 PM	5.0	5.3	5.6	5.8	5.1	5.5	0.4	7.5
11/25/91	1:45 PM	5.8	5.7	5.6	5.4	5.6	5.6	0.1	2.6
11/26/91	8:00 AM	5.1	5.0	4.9	4.6	4.7	4.9	0.2	4.3
11/26/91	9:00 AM	5.3	5.2	5.8	5.2	5.0	5.3	0.3	5.7
11/26/91	10:00 AM	5.0	5.0	4.9	5.1	4.8	4.8	0.3	6.6
11/26/91	11:10 AM	5.2	4.9	5.2	5.3	5.1	5.1	0.2	3.0
11/26/91	12:10 PM	4.9	4.7	4.5	4.5	4.9	4.7	0.2	4.3
11/26/91	1:10 PM	5.3	4.9	4.7	4.8	4.9	5.0	0.5	9.7
11/26/91	2:10 PM	5.0	4.6	5.0	4.7	4.7	4.8	0.2	3.9
11/28/91	8:05 AM	4.4	4.3	4.4	4.7	4.5	4.5	0.2	3.4
11/28/91	9:05 AM	4.3	4.2	4.2	4.4	4.1	4.2	0.1	2.7
11/28/91	10:05 AM	4.8	4.4	4.3	4.3	4.8	4.5	0.3	5.7
11/28/91	11:05 AM	5.1	4.7	5.1	4.7	5.2	5.0	0.2	4.9
11/28/91	12:10 PM	4.7	4.6	4.6	4.5	5.4	4.8	0.4	7.7
11/28/91	1:05 PM	5.1	5.2	5.1	5.2	5.1	5.1	0.1	1.1
11/28/91	2:05 PM	5.2	5.2	5.2	4.9	5.0	5.1	0.1	2.8
11/28/91	3:05 PM	5.4	5.8	4.9	5.1	4.9	5.2	0.4	7.3
11/28/91	4:05 PM	5.0	5.4	4.9	5.4	5.3	5.2	0.2	4.5
11/28/91	5:05 PM	4.9	5.0	5.6	5.3	4.7	5.1	0.4	6.9
11/29/91	10:25 AM	4.8	4.5	4.5	4.8	4.2	4.6	0.3	5.5

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/22/91	1:25 PM	5.6	5.7	5.4	5.6	5.7	5.6	0.1	2.3
11/22/91	2:40 PM	5.8	5.4	5.5	5.1	4.6	5.3	0.5	8.6
11/22/91	3:40 PM	5.4	5.8	6.2	5.8	5.8	5.6	0.3	5.1
11/23/91	8:10 AM	4.8	4.9	4.8	4.4	5.1	4.9	0.1	2.1
11/23/91	9:10 AM	5.0	5.1	5.1	4.6	4.4	4.8	0.3	6.6
11/23/91	10:10 AM	5.7	5.4	5.5	5.6	5.3	5.5	0.2	3.7
11/23/91	11:25 AM	6.0	6.3	4.9	5.4	6.4	5.4	0.4	7.3
11/23/91	12:25 PM	5.6	5.4	5.7	5.0	5.6	5.5	0.2	5.1
11/23/91	1:25 PM	5.9	5.1	5.6	5.1	5.7	5.5	0.4	6.6
11/23/91	2:35 PM	5.0	5.5	5.7	5.5	5.3	5.4	0.3	4.9
11/23/91	3:35 PM	5.7	4.8	5.4	5.0	4.1	5.4	0.5	9.7
11/25/91	7:35 AM	4.4	4.5	4.1	4.2	4.3	4.3	0.2	3.7
11/25/91	8:35 AM	4.9	4.9	5.0	5.3	4.7	5.0	0.2	4.4
11/25/91	9:40 AM	5.4	4.9	4.6	5.3	5.0	6.0	0.3	4.4
11/25/91	10:40 AM	5.2	5.4	4.9	4.8	4.6	6.0	0.3	6.4
11/25/91	11:40 AM	5.4	5.2	4.9	5.2	5.3	5.1	0.2	9.0
11/25/91	12:45 PM	5.7	5.1	5.2	5.6	4.9	5.3	0.3	6.4
11/25/91	1:45 PM	5.4	5.5	5.3	5.7	5.7	5.5	0.2	3.2
11/26/91	8:00 AM	4.4	4.6	4.6	4.8	4.5	4.6	0.1	3.2
11/26/91	9:00 AM	4.2	5.2	5.1	5.2	5.2	5.0	0.4	8.8
11/26/91	10:00 AM	4.8	5.5	4.8	5.4	5.3	5.2	0.3	6.5
11/26/91	11:10 AM	5.0	5.0	5.1	5.2	5.3	5.1	0.1	2.5
11/26/91	12:10 PM	5.2	5.4	5.1	5.7	5.4	5.4	0.2	4.3
11/26/91	1:10 PM	5.3	5.8	5.0	5.4	5.6	5.4	0.3	5.6
11/26/91	2:10 PM	5.1	4.9	5.0	5.1	4.9	5.0	0.1	2.0
11/28/91	8:05 AM	4.7	4.2	4.0	3.7	3.9	4.1	0.4	9.3
11/28/91	9:05 AM	4.2	4.5	4.6	4.4	4.4	4.4	0.1	3.4
11/28/91	10:05 AM	4.7	4.7	4.5	4.8	4.4	4.6	0.2	3.6
11/28/91	11:05 AM	5.1	4.9	4.8	5.1	5.4	5.1	0.2	4.5
11/28/91	12:10 PM	5.1	5.3	4.7	4.5	4.7	4.9	0.3	6.8
11/28/91	1:05 PM	4.9	4.9	4.5	5.0	5.0	4.7	0.3	6.8
11/28/91	2:05 PM	5.2	4.9	5.2	4.9	4.5	4.8	0.4	8.5
11/28/91	3:05 PM	5.1	4.9	5.5	5.0	4.8	5.1	0.3	5.3
11/28/91	4:05 PM	5.2	4.9	4.9	4.9	5.4	5.1	0.2	4.5
11/28/91	5:05 PM	4.6	5.4	5.2	5.2	5.3	5.1	0.3	6.1
11/29/91	10:25 AM	4.3	5.0	4.4	5.1	5.2	4.9	0.5	10.0

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4936A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/29/91	2:15 PM	5.7	5.4	6.9	6.0	6.0	6.6	0.4	7.3
11/29/91	3:45 PM	6.9	5.4	5.1	6.2	6.6	6.6	0.4	7.7
11/29/91	4:15 PM	6.9	5.8	5.8	6.3	6.0	6.0	0.2	3.6
11/29/91	5:45 PM	6.3	6.4	6.0	6.0	5.7	6.1	0.3	4.6
11/29/91	6:45 PM	5.5	6.1	6.9	6.6	5.7	5.7	0.3	4.6
11/29/91	7:55 PM	5.6	6.5	5.0	5.3	5.3	5.3	0.2	4.3
11/29/91	8:55 AM	6.0	5.4	6.3	6.4	5.1	5.6	0.5	8.7
11/30/91	9:00 AM	5.2	5.4	5.2	5.0	5.4	5.2	0.2	3.2
11/30/91	9:00 AM	6.6	5.3	4.8	4.6	5.3	5.1	0.4	8.0
11/30/91	10:00 AM	4.6	5.1	5.2	5.4	4.9	5.0	0.3	6.1
11/30/91	11:00 AM	5.3	5.6	6.7	4.6	5.2	5.2	0.5	8.7
11/30/91	12:00 PM	5.1	5.5	6.4	5.1	5.6	5.3	0.2	3.9
11/30/91	1:00 PM	4.8	4.9	4.6	4.7	5.3	4.9	0.3	5.6
11/30/91	2:00 PM	5.7	4.9	5.5	5.0	5.3	5.3	0.3	6.3
11/30/91	3:00 PM	5.3	4.7	4.9	4.8	4.9	4.9	0.2	4.6
11/30/91	4:00 PM	5.6	4.7	5.6	5.1	5.2	5.2	0.4	7.2
11/30/91	5:00 PM	4.8	5.3	4.6	5.4	4.9	5.0	0.3	6.8
11/30/91	6:00 PM	4.8	4.7	5.8	5.3	5.1	5.1	0.4	8.5
11/30/91	7:00 PM	5.0	5.5	4.6	5.6	5.2	5.2	0.4	7.8
11/30/91	8:00 PM	5.1	5.0	5.1	5.7	4.7	5.1	0.4	7.1
11/30/91	9:00 PM	5.3	4.6	5.5	5.2	5.0	5.1	0.3	6.7
12/1/91	7:50 AM	4.8	4.3	4.3	4.7	4.9	4.6	0.3	6.1
12/1/91	8:50 AM	5.0	4.8	5.0	4.7	4.3	4.8	0.3	6.1
12/1/91	9:50 AM	4.8	4.1	4.2	4.7	4.4	4.4	0.3	6.9
12/1/91	10:50 AM	4.6	5.1	4.9	4.6	4.1	4.7	0.4	8.1
12/1/91	11:50 AM	4.9	4.6	4.7	4.6	4.7	4.9	0.6	8.6
12/1/91	12:50 PM	5.2	5.0	5.0	5.3	5.4	5.2	0.2	3.5
12/1/91	1:45 PM	4.6	5.0	4.6	4.8	4.8	4.7	0.2	4.6
12/1/91	2:45 PM	4.4	4.6	4.8	5.0	4.6	4.7	0.2	4.9
12/1/91	4:10 PM	5.6	5.6	4.8	5.1	4.8	5.2	0.4	7.8
12/1/91	5:10 PM	5.6	4.6	5.3	6.0	5.4	5.4	0.6	10.3
12/1/91	6:10 PM	5.8	5.3	6.7	6.2	5.0	5.4	0.3	6.3
12/1/91	7:25 PM	5.6	6.0	5.3	5.6	5.5	5.4	0.2	4.1
12/1/91	8:25 PM	5.6	5.6	5.7	4.9	5.1	5.4	0.4	6.6
12/1/91	9:25 PM	5.0	5.3	5.0	5.4	5.7	5.3	0.3	5.6

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/29/91	2:15 PM	5.6	5.4	5.1	5.3	5.2	5.3	0.2	3.6
11/29/91	3:15 PM	5.8	6.0	6.3	5.8	5.9	6.0	0.2	3.5
11/29/91	4:15 PM	6.1	6.4	6.0	5.8	6.1	6.1	0.2	3.6
11/29/91	5:45 PM	6.0	5.6	6.4	6.5	5.8	5.9	0.4	6.1
11/29/91	6:45 PM	5.8	5.0	5.0	4.8	4.8	5.1	0.4	8.2
11/29/91	7:55 PM	5.9	5.4	5.6	5.8	5.2	5.6	0.3	5.1
11/29/91	8:55 AM	5.0	5.5	5.9	5.3	6.4	5.6	0.5	9.7
11/30/91	8:00 AM	5.0	5.6	5.7	4.8	5.1	5.2	0.4	7.1
11/30/91	9:00 AM	5.9	4.9	6.3	5.6	5.7	5.7	0.5	9.1
11/30/91	10:00 AM	5.6	5.5	4.8	5.0	5.7	5.3	0.4	7.4
11/30/91	11:00 AM	4.9	5.2	5.2	5.1	4.6	5.0	0.3	5.1
11/30/91	12:00 PM	5.8	5.0	5.6	5.6	5.4	5.5	0.3	5.4
11/30/91	1:00 PM	5.2	5.1	5.7	5.2	5.0	5.2	0.3	5.2
11/30/91	2:00 PM	5.6	5.7	6.0	5.6	6.1	5.6	0.4	7.1
11/30/91	3:00 PM	5.5	5.0	5.4	5.3	5.4	5.3	0.2	3.6
11/30/91	4:00 PM	5.8	5.7	5.4	5.3	5.0	5.5	0.4	6.4
11/30/91	5:00 PM	5.3	4.7	5.2	4.8	5.8	5.2	0.4	8.5
11/30/91	6:00 PM	5.2	5.5	5.6	4.9	5.6	5.4	0.3	5.7
11/30/91	7:00 PM	5.1	5.6	5.4	5.4	5.6	5.4	0.2	3.8
11/30/91	8:00 PM	5.6	4.9	5.0	5.2	4.7	5.1	0.3	6.7
11/30/91	9:00 PM	4.9	5.1	5.8	5.4	5.7	5.4	0.4	7.1
12/1/91	7:50 AM	5.1	5.0	5.2	5.0	4.6	5.0	0.2	4.6
12/1/91	8:50 AM	4.9	5.2	4.8	4.9	4.8	4.9	0.2	3.3
12/1/91	9:50 AM	4.7	4.0	4.7	5.0	4.9	4.7	0.4	8.4
12/1/91	10:50 AM	5.2	5.5	4.4	4.7	5.4	5.0	0.5	9.4
12/1/91	11:50 AM	5.2	5.5	5.4	4.8	5.1	5.2	0.3	5.3
12/1/91	12:50 PM	4.7	5.0	5.8	5.2	6.0	5.3	0.6	10.2
12/1/91	1:45 PM	5.5	5.6	4.7	5.4	5.0	5.2	0.4	7.2
12/1/91	2:45 PM	5.5	5.4	5.5	5.3	5.6	5.5	0.1	2.1
12/1/91	4:10 PM	5.6	5.6	5.4	5.4	5.1	5.6	0.3	5.1
12/1/91	5:10 PM	5.5	5.9	5.4	5.2	5.4	5.9	0.4	7.4
12/1/91	6:10 PM	5.4	5.7	5.7	5.8	5.9	5.7	0.2	3.3
12/1/91	7:25 PM	5.5	5.7	5.2	5.3	5.6	5.4	0.2	3.6
12/1/91	8:25 PM	5.6	5.5	5.8	5.3	5.5	5.5	0.2	3.2
12/1/91	9:25 PM	5.7	5.6	5.1	5.6	5.9	5.6	0.3	5.3

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

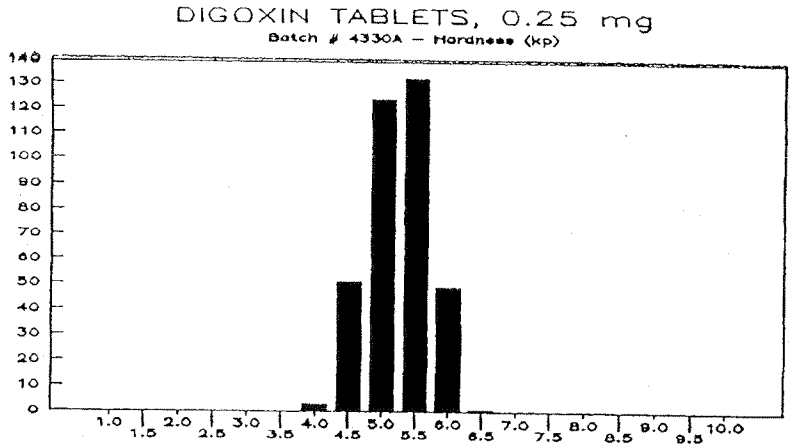
DIGOXIN TABLETS, 0.25 mg - Batch # 4331A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
12/2/94	10:00 AM	5.2	5.1	5.2	5.1	1.7	5.2	0.3	5.5
12/2/94	11:00 AM	1.6	1.8	1.9	5.2	1.9	1.9	0.2	1.1
12/2/94	12:00 PM	1.2	1.6	1.2	1.3	1.2	1.3	0.2	1.0
12/2/94	1:00 PM	1.8	5.1	5.2	1.6	5.3	5.1	0.3	6.8
12/2/94	2:05 PM	5.0	5.0	1.6	1.4	1.5	1.7	0.2	5.1
12/2/94	3:10 PM	1.3	1.3	1.3	1.1	1.2	1.3	0.1	1.6
12/3/94	7:20 AM	1.6	1.6	1.3	1.5	1.5	1.5	0.1	2.7
12/3/94	8:20 AM	1.9	5.1	1.1	1.9	1.5	1.8	0.3	6.2
12/3/94	9:20 AM	1.5	5.1	1.3	1.1	1.8	1.6	0.1	8.7
12/3/94	10:20 AM	1.6	1.9	1.8	5.2	1.1	1.8	0.3	6.3
12/3/94	11:35 AM	5.0	5.0	1.6	5.0	1.8	1.9	0.2	9.7
12/3/94	12:35 PM	5.0	1.7	5.0	1.6	5.0	1.9	0.2	1.0
12/3/94	1:35 PM	1.6	1.7	5.6	1.7	1.9	1.9	0.1	8.7
12/3/94	2:35 PM	1.9	5.0	1.9	1.7	5.0	1.9	0.1	2.5
12/5/94	7:55 AM	3.9	3.9	1.2	1.1	3.9	1.0	0.1	3.5
12/5/94	8:55 AM	1.9	1.9	3.7	1.2	1.3	1.2	0.3	6.1
12/5/94	9:55 AM	1.7	1.7	1.1	1.0	1.6	1.1	0.3	7.7
12/5/94	11:00 AM	1.3	1.6	1.2	1.5	1.2	1.1	0.2	1.2
12/5/94	11:50 AM	1.7	1.5	1.6	1.5	1.8	1.6	0.1	2.8
12/5/94	12:50 PM	5.1	1.6	1.8	1.7	1.5	1.7	0.2	1.9
12/5/94	1:50 PM	1.8	5.5	6.2	5.6	5.3	5.6	0.5	9.9
12/5/94	2:50 PM	5.3	1.7	5.2	1.7	1.1	1.9	0.1	7.8
12/5/94	3:50 PM	1.9	5.1	1.8	1.8	1.7	1.9	0.3	5.6
12/5/94	4:50 PM	1.8	1.9	1.8	1.8	1.3	1.7	0.3	6.0
12/5/94	5:30 PM	1.5	1.7	1.9	1.9	5.2	1.9	0.3	6.1
12/6/94	7:50 AM	1.3	1.1	3.9	1.5	1.5	1.3	0.2	5.8
12/6/94	9:35 AM	1.7	1.6	1.3	1.1	1.9	1.6	0.2	5.2
12/6/94	10:35 AM	1.3	1.2	1.3	1.7	1.7	1.1	0.2	5.1
12/6/94	11:35 AM	1.8	5.0	1.6	1.7	1.9	1.8	0.2	9.3
12/6/94	12:35 PM	5.1	5.2	5.1	5.1	5.0	5.2	0.2	3.1
12/6/94	1:40 PM	5.5	1.8	5.0	5.5	5.5	5.3	0.2	6.1
12/6/94	2:40 PM	5.0	5.5	5.1	5.2	5.0	5.2	0.2	1.1
12/6/94	3:35 PM	5.1	5.1	1.1	1.9	5.0	5.0	0.1	7.1
12/7/94	7:50 AM	1.5	5.0	1.8	1.2	5.1	1.8	0.2	5.0
12/7/94	8:50 AM	5.0	5.0	1.9	1.8	1.6	1.9	0.2	3.1
12/7/94	9:50 AM	5.3	5.0	1.8	5.0	1.9	5.0	0.2	3.7
12/7/94	11:35 AM	1.1	1.2	1.1	1.5	3.9	1.2	0.2	5.7

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
12/2/94	10:00 AM	1.5	5.5	1.6	1.3	5.0	1.8	0.6	10.2
12/2/94	11:00 AM	1.7	5.3	5.3	1.3	5.1	5.2	0.5	8.9
12/2/94	12:00 PM	5.1	1.8	1.7	1.6	1.8	1.8	0.2	3.9
12/2/94	1:00 PM	5.3	5.8	1.9	5.0	5.3	5.1	0.5	8.5
12/2/94	2:05 PM	1.9	5.1	5.6	1.9	1.9	5.1	0.3	6.0
12/2/94	3:10 PM	1.1	1.3	1.1	1.1	1.5	1.3	0.2	3.5
12/3/94	7:20 AM	1.5	5.2	5.1	1.6	5.5	5.0	0.1	2.1
12/3/94	8:20 AM	5.0	5.1	5.3	5.6	5.5	5.1	0.2	1.3
12/3/94	9:20 AM	5.0	5.2	5.1	5.5	5.6	5.3	0.2	1.5
12/3/94	10:20 AM	5.2	5.2	5.3	5.2	5.5	5.3	0.1	2.5
12/3/94	11:35 AM	1.8	5.6	5.2	1.7	5.0	5.0	0.3	4.1
12/3/94	12:35 PM	1.9	5.1	5.3	5.6	5.2	5.1	0.4	7.1
12/3/94	1:35 PM	1.6	5.1	5.6	4.1	1.8	5.2	0.6	11.4
12/3/94	2:35 PM	5.5	1.9	5.3	1.8	1.3	5.0	0.5	9.1
12/6/94	7:55 AM	1.0	1.2	1.3	1.3	3.9	1.1	0.2	1.1
12/5/94	8:55 AM	1.5	1.6	5.2	5.1	5.3	5.0	0.1	8.1
12/5/94	9:55 AM	1.7	1.6	1.9	5.3	1.9	1.9	0.3	5.5
12/5/94	11:00 AM	5.0	5.0	5.2	1.3	5.2	1.9	0.1	7.5
12/5/94	11:50 AM	5.6	1.9	1.7	5.1	1.7	5.1	0.1	8.2
12/5/94	12:50 PM	5.1	5.1	5.2	5.0	5.0	5.1	0.2	3.3
12/5/94	1:50 PM	1.6	5.8	1.7	6.0	1.7	5.2	0.7	13.2
12/5/94	2:50 PM	5.3	5.2	5.0	5.2	1.9	5.1	0.2	3.2
12/5/94	3:50 PM	5.6	1.8	1.5	5.5	5.2	5.1	0.5	9.1
12/5/94	4:50 PM	5.6	5.8	5.6	5.2	5.0	5.1	0.3	6.0
12/5/94	5:30 PM	5.2	5.1	5.3	5.5	5.1	5.2	0.2	3.2
12/6/94	7:50 AM	1.9	1.8	5.2	1.9	5.0	5.0	0.2	3.1
12/6/94	9:35 AM	1.8	1.6	5.3	1.7	1.7	1.8	0.3	5.8
12/6/94	10:35 AM	5.0	1.9	5.1	5.1	5.3	5.0	0.4	7.8
12/6/94	11:35 AM	1.8	5.3	1.7	1.5	1.7	1.8	0.9	6.2
12/6/94	12:35 PM	5.6	1.8	5.2	5.2	1.9	5.1	0.3	6.1
12/6/94	1:40 PM	5.3	5.9	5.3	5.9	5.6	5.5	0.3	1.9
12/6/94	2:40 PM	5.3	5.7	5.5	5.3	5.1	5.1	0.2	1.2
12/6/94	3:35 PM	1.9	5.9	5.1	5.7	5.8	5.7	0.5	8.1
12/7/94	7:50 AM	1.1	5.3	5.1	1.8	5.1	1.9	0.1	7.1
12/7/94	8:50 AM	5.3	1.7	6.0	5.2	5.3	5.1	0.3	5.0
12/7/94	9:50 AM	5.5	5.1	1.9	5.2	5.1	5.2	0.2	1.2
12/7/94	11:35 AM	5.1	5.0	5.2	5.0	1.5	5.0	0.3	6.1


DIGOXIN TABLETS, 0.25 mg
Batch # 4330A – Hardness (kp)
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
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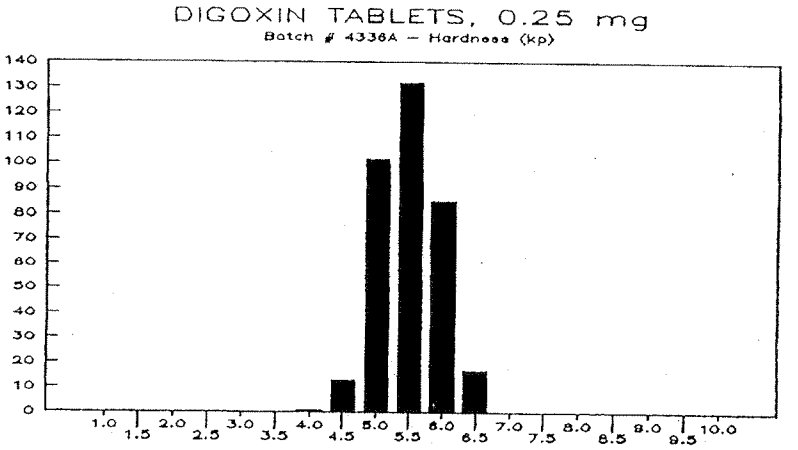
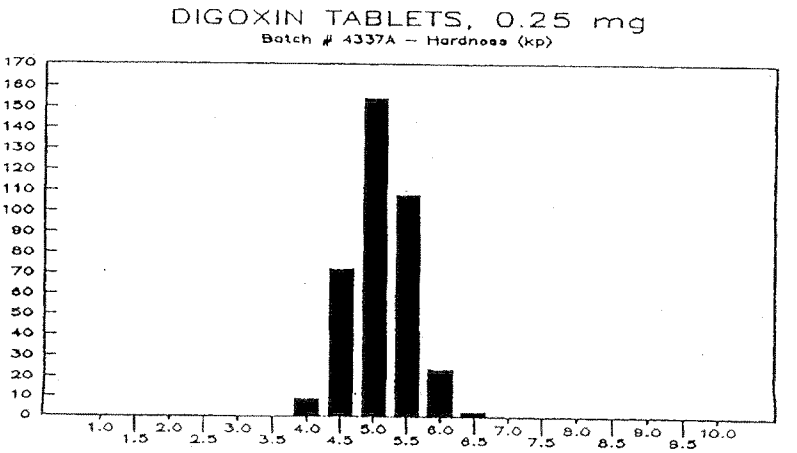

DIGOXIN TABLETS, 0.25 mg
Batch # 4336A – Hardness (kp)
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0


DIGOXIN TABLETS, 0.25 mg
Batch # 4337A – Hardness (kp)
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4330A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/22/91	1:25 PM	3.12	3.13	3.13	3.12	3.11	3.12	0.01	0.3
11/22/91	2:10 PM	3.08	3.10	3.10	3.11	3.09	3.10	0.01	0.4
11/22/91	3:10 PM	3.12	3.10	3.10	3.11	3.11	3.11	0.01	0.3
11/23/91	8:10 AM	3.09	3.09	3.10	3.09	3.10	3.09	0.01	0.2
11/23/91	9:10 AM	3.09	3.08	3.08	3.10	3.09	3.09	0.01	0.3
11/23/91	10:10 AM	3.12	3.10	3.10	3.12	3.09	3.11	0.01	0.4
11/23/91	11:25 AM	3.12	3.13	3.11	3.10	3.12	3.12	0.01	0.4
11/23/91	12:25 PM	3.11	3.09	3.10	3.09	3.09	3.09	0.01	0.4
11/23/91	1:25 PM	3.10	3.11	3.08	3.09	3.10	3.10	0.01	0.4
11/23/91	2:35 PM	3.08	3.09	3.11	3.09	3.09	3.09	0.01	0.4
11/23/91	3:35 PM	3.10	3.10	3.09	3.08	3.07	3.09	0.01	0.4
11/25/91	7:35 AM	3.12	3.12	3.16	3.12	3.14	3.13	0.02	0.6
11/25/91	8:35 AM	3.11	3.10	3.13	3.11	3.12	3.11	0.01	0.4
11/25/91	9:10 AM	3.13	3.13	3.12	3.13	3.12	3.13	0.01	0.2
11/25/91	10:10 AM	3.12	3.14	3.13	3.10	3.15	3.13	0.02	0.6
11/25/91	11:10 AM	3.10	3.12	3.09	3.11	3.10	3.10	0.01	0.4
11/25/91	12:15 PM	3.13	3.12	3.13	3.10	3.09	3.11	0.02	0.7
11/25/91	1:15 PM	3.11	3.10	3.13	3.11	3.12	3.11	0.01	0.4
11/26/91	8:00 AM	3.13	3.15	3.11	3.11	3.12	3.12	0.02	0.5
11/26/91	9:00 AM	3.12	3.10	3.13	3.11	3.11	3.11	0.01	0.4
11/26/91	10:00 AM	3.12	3.11	3.12	3.11	3.12	3.12	0.01	0.2
11/26/91	11:10 AM	3.12	3.11	3.11	3.13	3.12	3.12	0.01	0.3
11/26/91	12:10 PM	3.12	3.10	3.10	3.11	3.12	3.11	0.01	0.3
11/26/91	1:10 PM	3.13	3.10	3.12	3.14	3.13	3.12	0.02	0.5
11/26/91	2:10 PM	3.10	3.13	3.09	3.10	3.10	3.10	0.02	0.5
11/28/91	8:05 AM	3.12	3.14	3.16	3.16	3.14	3.14	0.02	0.5
11/28/91	9:05 AM	3.14	3.15	3.13	3.09	3.14	3.13	0.02	0.7
11/28/91	10:05 AM	3.10	3.10	3.09	3.12	3.11	3.10	0.01	0.4
11/28/91	11:05 AM	3.11	3.12	3.13	3.15	3.12	3.13	0.02	0.5
11/28/91	12:10 PM	3.12	3.09	3.12	3.08	3.09	3.10	0.02	0.6
11/28/91	1:05 PM	3.12	3.11	3.12	3.11	3.12	3.12	0.01	0.2
11/28/91	2:05 PM	3.11	3.13	3.11	3.12	3.12	3.12	0.01	0.3
11/28/91	3:05 PM	3.12	3.07	3.12	3.11	3.07	3.10	0.03	0.8
11/28/91	4:05 PM	3.15	3.13	3.14	3.15	3.15	3.14	0.01	0.3
11/28/91	5:05 PM	3.08	3.09	3.08	3.10	3.09	3.09	0.01	0.3
11/29/91	10:25 AM	3.10	3.12	3.12	3.10	3.11	3.11	0.01	0.3

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/22/91	1:25 PM	3.12	3.11	3.12	3.10	3.11	3.11	0.01	0.3
11/22/91	2:10 PM	3.12	3.15	3.13	3.12	3.10	3.12	0.02	0.6
11/22/91	3:10 PM	3.13	3.13	3.14	3.12	3.14	3.13	0.01	0.3
11/23/91	8:10 AM	3.13	3.11	3.11	3.13	3.10	3.12	0.01	0.4
11/23/91	9:10 AM	3.10	3.10	3.07	3.09	3.11	3.09	0.02	0.5
11/23/91	10:10 AM	3.13	3.09	3.12	3.12	3.11	3.11	0.02	0.5
11/23/91	11:25 AM	3.12	3.09	3.12	3.11	3.10	3.11	0.01	0.4
11/23/91	12:25 PM	3.10	3.11	3.12	3.10	3.11	3.11	0.01	0.3
11/23/91	1:25 PM	3.09	3.13	3.10	3.11	3.10	3.11	0.02	0.5
11/23/91	2:35 PM	3.09	3.09	3.10	3.08	3.07	3.08	0.01	0.4
11/23/91	3:35 PM	3.10	3.11	3.09	3.09	3.10	3.10	0.01	0.3
11/25/91	7:35 AM	3.11	3.11	3.12	3.09	3.11	3.11	0.01	0.4
11/25/91	8:35 AM	3.09	3.11	3.14	3.12	3.12	3.12	0.02	0.6
11/25/91	9:10 AM	3.10	3.08	3.13	3.10	3.10	3.10	0.02	0.6
11/25/91	10:10 AM	3.11	3.13	3.13	3.10	3.11	3.12	0.01	0.4
11/25/91	11:10 AM	3.10	3.10	3.10	3.13	3.19	3.12	0.03	1.1
11/25/91	12:15 PM	3.12	3.09	3.11	3.10	3.10	3.10	0.01	0.4
11/25/91	1:15 PM	3.10	3.09	3.10	3.12	3.12	3.11	0.01	0.4
11/26/91	8:00 AM	3.11	3.10	3.15	3.13	3.11	3.12	0.02	0.6
11/26/91	9:00 AM	3.09	3.11	3.12	3.13	3.12	3.12	0.02	0.6
11/26/91	10:00 AM	3.12	3.11	3.12	3.10	3.12	3.12	0.01	0.4
11/26/91	11:10 AM	3.10	3.09	3.12	3.13	3.11	3.11	0.02	0.6
11/26/91	12:10 PM	3.13	3.13	3.12	3.11	3.12	3.12	0.01	0.3
11/26/91	1:10 PM	3.13	3.12	3.11	3.12	3.13	3.12	0.01	0.3
11/26/91	2:10 PM	3.10	3.09	3.10	3.12	3.10	3.10	0.01	0.4
11/28/91	8:05 AM	3.14	3.11	3.15	3.13	3.13	3.14	0.01	0.2
11/28/91	9:05 AM	3.12	3.11	3.10	3.10	3.10	3.11	0.01	0.3
11/28/91	10:05 AM	3.10	3.10	3.11	3.10	3.12	3.11	0.01	0.3
11/28/91	11:05 AM	3.10	3.12	3.09	3.11	3.10	3.10	0.01	0.4
11/28/91	12:10 PM	3.08	3.10	3.09	3.10	3.11	3.10	0.01	0.4
11/28/91	1:05 PM	3.07	3.04	3.11	3.08	3.06	3.08	0.03	1.1
11/28/91	2:05 PM	3.08	3.09	3.13	3.11	3.10	3.10	0.02	0.5
11/28/91	3:05 PM	3.08	3.11	3.09	3.08	3.08	3.09	0.01	0.4
11/28/91	4:05 PM	3.12	3.11	3.12	3.10	3.11	3.11	0.01	0.3
11/28/91	5:05 PM	3.11	3.11	3.11	3.12	3.12	3.11	0.01	0.2
11/29/91	10:25 AM	3.14	3.13	3.15	3.15	3.13	3.14	0.01	0.3

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg - Batch # 4336A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/29/94	2:45 PM	3.13	3.12	3.12	3.13	3.12	3.12	0.01	0.2
11/29/94	3:45 PM	3.13	3.15	3.13	3.14	3.13	3.14	0.01	0.3
11/29/94	4:45 PM	3.16	3.13	3.12	3.13	3.13	3.13	0.02	0.6
11/29/94	5:45 PM	3.14	3.15	3.13	3.15	3.14	3.14	0.01	0.3
11/29/94	6:45 PM	3.13	3.16	3.09	3.12	3.11	3.12	0.03	0.8
11/29/94	7:55 PM	3.11	3.11	3.10	3.13	3.10	3.11	0.01	0.4
11/29/94	8:55 PM	3.11	3.14	3.10	3.10	3.13	3.12	0.02	0.6
11/30/94	8:00 AM	3.12	3.16	3.13	3.15	3.12	3.15	0.02	0.7
11/30/94	9:00 AM	3.16	3.14	3.15	3.16	3.16	3.15	0.01	0.3
11/30/94	10:00 AM	3.15	3.14	3.13	3.12	3.13	3.13	0.01	0.4
11/30/94	11:00 AM	3.15	3.16	3.14	3.13	3.11	3.14	0.02	0.6
11/30/94	12:00 PM	3.16	3.15	3.16	3.17	3.17	3.16	0.01	0.3
11/30/94	1:00 PM	3.11	3.16	3.14	3.12	3.12	3.13	0.02	0.6
11/30/94	2:00 PM	3.14	3.15	3.12	3.16	3.14	3.14	0.01	0.5
11/30/94	3:00 PM	3.12	3.13	3.14	3.15	3.15	3.14	0.01	0.4
11/30/94	4:00 PM	3.12	3.13	3.15	3.10	3.14	3.13	0.02	0.6
11/30/94	5:00 PM	3.14	3.12	3.13	3.15	3.13	3.13	0.01	0.4
11/30/94	6:00 PM	3.13	3.15	3.16	3.14	3.11	3.14	0.02	0.6
11/30/94	7:00 PM	3.13	3.16	3.15	3.11	3.13	3.14	0.01	0.4
11/30/94	8:00 PM	3.13	3.15	3.16	3.15	3.15	3.15	0.01	0.3
11/30/94	9:00 PM	3.14	3.16	3.12	3.14	3.15	3.14	0.01	0.5
12/1/94	7:50 AM	3.15	3.15	3.16	3.16	3.16	3.16	0.01	0.2
12/1/94	8:50 AM	3.16	3.16	3.15	3.16	3.16	3.16	0.00	0.1
12/1/94	9:50 AM	3.15	3.16	3.16	3.14	3.14	3.15	0.01	0.3
12/1/94	10:50 AM	3.13	3.15	3.17	3.13	3.15	3.15	0.02	0.5
12/1/94	11:50 AM	3.13	3.14	3.14	3.13	3.16	3.14	0.01	0.4
12/1/94	12:50 PM	3.13	3.17	3.17	3.16	3.15	3.16	0.02	0.6
12/1/94	1:45 PM	3.16	3.13	3.13	3.12	3.14	3.13	0.01	0.4
12/1/94	2:45 PM	3.13	3.12	3.13	3.14	3.10	3.12	0.02	0.6
12/1/94	4:10 PM	3.15	3.15	3.16	3.16	3.16	3.15	0.01	0.2
12/1/94	5:10 PM	3.14	3.15	3.16	3.18	3.19	3.16	0.02	0.7
12/1/94	6:10 PM	3.16	3.17	3.15	3.14	3.17	3.16	0.01	0.4
12/1/94	7:25 PM	3.16	3.16	3.15	3.17	3.18	3.16	0.01	0.4
12/1/94	8:25 PM	3.17	3.16	3.15	3.15	3.17	3.16	0.01	0.3
12/1/94	9:25 PM	3.15	3.15	3.16	3.13	3.16	3.15	0.01	0.4

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/29/94	2:45 PM	3.13	3.14	3.11	3.13	3.13	3.13	0.01	0.4
11/29/94	3:45 PM	3.15	3.14	3.14	3.14	3.15	3.14	0.01	0.2
11/29/94	4:45 PM	3.16	3.16	3.13	3.14	3.14	3.15	0.01	0.4
11/29/94	5:45 PM	3.15	3.17	3.16	3.15	3.17	3.16	0.01	0.3
11/29/94	6:45 PM	3.11	3.12	3.10	3.11	3.13	3.11	0.01	0.4
11/29/94	7:55 PM	3.11	3.13	3.13	3.14	3.13	3.13	0.01	0.4
11/29/94	8:55 PM	3.12	3.11	3.13	3.10	3.16	3.12	0.02	0.7
11/30/94	8:00 AM	3.14	3.13	3.15	3.15	3.14	3.14	0.01	0.3
11/30/94	9:00 AM	3.13	3.16	3.15	3.15	3.16	3.15	0.01	0.4
11/30/94	10:00 AM	3.12	3.13	3.10	3.11	3.14	3.12	0.02	0.5
11/30/94	11:00 AM	3.11	3.10	3.12	3.11	3.13	3.11	0.01	0.4
11/30/94	12:00 PM	3.11	3.13	3.11	3.12	3.11	3.12	0.01	0.3
11/30/94	1:00 PM	3.07	3.15	3.12	3.09	3.12	3.11	0.03	1.0
11/30/94	2:00 PM	3.14	3.13	3.15	3.13	3.14	3.14	0.01	0.3
11/30/94	3:00 PM	3.13	3.11	3.10	3.13	3.14	3.12	0.02	0.6
11/30/94	4:00 PM	3.10	3.11	3.12	3.11	3.12	3.11	0.01	0.3
11/30/94	5:00 PM	3.13	3.11	3.13	3.12	3.11	3.12	0.01	0.3
11/30/94	6:00 PM	3.14	3.11	3.13	3.12	3.11	3.12	0.01	0.4
11/30/94	7:00 PM	3.12	3.14	3.12	3.13	3.14	3.13	0.01	0.3
11/30/94	8:00 PM	3.12	3.13	3.10	3.11	3.12	3.12	0.01	0.4
11/30/94	9:00 PM	3.14	3.15	3.12	3.15	3.14	3.14	0.01	0.4
12/1/94	7:50 AM	3.14	3.14	3.16	3.13	3.13	3.14	0.01	0.4
12/1/94	8:50 AM	3.14	3.13	3.13	3.13	3.12	3.13	0.01	0.2
12/1/94	9:50 AM	3.11	3.09	3.10	3.12	3.10	3.10	0.01	0.4
12/1/94	10:50 AM	3.12	3.13	3.13	3.12	3.11	3.12	0.01	0.3
12/1/94	11:50 AM	3.12	3.14	3.12	3.13	3.11	3.12	0.01	0.4
12/1/94	12:50 PM	3.11	3.16	3.15	3.16	3.15	3.14	0.02	0.6
12/1/94	1:45 PM	3.14	3.15	3.14	3.12	3.12	3.13	0.01	0.4
12/1/94	2:45 PM	3.13	3.13	3.14	3.12	3.11	3.13	0.01	0.4
12/1/94	4:10 PM	3.12	3.14	3.13	3.14	3.13	3.13	0.01	0.3
12/1/94	5:10 PM	3.12	3.11	3.12	3.11	3.12	3.12	0.01	0.2
12/1/94	6:10 PM	3.15	3.13	3.12	3.12	3.13	3.13	0.01	0.4
12/1/94	7:25 PM	3.15	3.12	3.12	3.12	3.13	3.13	0.01	0.4
12/1/94	8:25 PM	3.11	3.15	3.12	3.13	3.12	3.13	0.02	0.5
12/1/94	9:25 PM	3.13	3.13	3.11	3.11	3.14	3.12	0.01	0.4

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

[illegible]

Compression - Thickness (mm) - Front

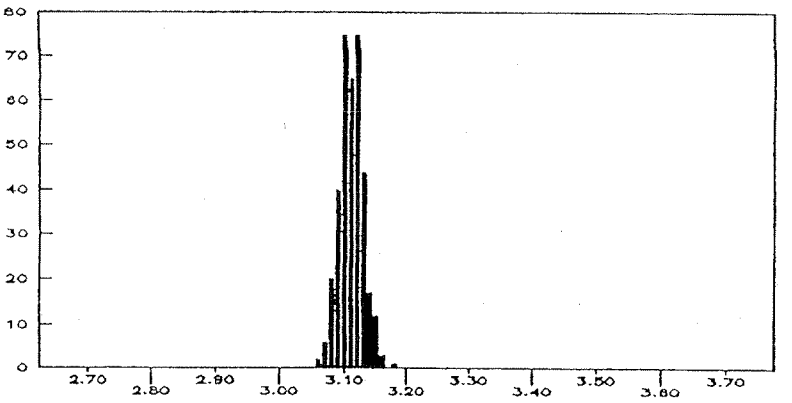
Date	Time	1	2	3	4	5	Average	St Dev.	RSD
12/2/91	10:00 AM	3.11	3.11	3.12	3.11	3.10	3.11	0.01	0.2
12/2/91	11:00 AM	3.16	3.13	3.15	3.11	3.11	3.14	0.02	0.6
12/2/91	12:00 PM	3.12	3.11	3.12	3.10	3.11	3.11	0.01	0.3
12/2/91	1:00 PM	3.17	3.19	3.17	3.15	3.18	3.17	0.01	0.5
12/2/91	2:05 PM	3.14	3.15	3.15	3.15	3.15	3.15	0.00	0.1
12/2/91	3:40 PM	3.09	3.06	3.06	3.07	3.10	3.08	0.02	0.6
12/3/91	7:20 AM	3.19	3.20	3.20	3.19	3.18	3.19	0.01	0.3
12/3/91	8:20 AM	3.17	3.17	3.20	3.19	3.18	3.18	0.01	0.4
12/3/91	9:20 AM	3.17	3.17	3.17	3.15	3.16	3.16	0.01	0.3
12/3/91	10:20 AM	3.14	3.17	3.16	3.16	3.17	3.16	0.01	0.4
12/3/91	11:35 AM	3.18	3.18	3.18	3.19	3.17	3.18	0.01	0.2
12/3/91	12:35 PM	3.19	3.18	3.17	3.16	3.16	3.17	0.01	0.4
12/3/91	1:35 PM	3.17	3.16	3.19	3.18	3.16	3.17	0.01	0.4
12/3/91	2:35 PM	3.18	3.16	3.16	3.16	3.14	3.16	0.01	0.4
12/5/91	7:55 AM	3.17	3.18	3.18	3.20	3.16	3.18	0.01	0.6
12/5/91	8:55 AM	3.18	3.17	3.17	3.19	3.19	3.18	0.01	0.3
12/5/91	9:55 AM	3.18	3.17	3.16	3.18	3.19	3.18	0.01	0.4
12/5/91	11:00 AM	3.17	3.16	3.14	3.15	3.18	3.16	0.02	0.5
12/5/91	11:50 AM	3.15	3.16	3.16	3.15	3.15	3.15	0.01	0.2
12/5/91	12:50 PM	3.16	3.15	3.15	3.17	3.15	3.16	0.01	0.3
12/5/91	1:50 PM	3.13	3.15	3.13	3.16	3.13	3.14	0.01	0.5
12/5/91	2:50 PM	3.14	3.15	3.13	3.13	3.14	3.14	0.01	0.3
12/5/91	3:50 PM	3.16	3.15	3.14	3.15	3.16	3.15	0.01	0.2
12/5/91	4:50 PM	3.15	3.15	3.14	3.15	3.13	3.14	0.01	0.3
12/5/91	5:30 PM	3.14	3.15	3.12	3.14	3.14	3.15	0.01	0.4
12/6/91	7:50 AM	3.13	3.15	3.13	3.14	3.13	3.14	0.01	0.3
12/6/91	9:35 AM	3.13	3.15	3.14	3.15	3.15	3.14	0.01	0.3
12/6/91	10:35 AM	3.13	3.14	3.14	3.13	3.12	3.13	0.01	0.3
12/6/91	11:35 AM	3.15	3.14	3.14	3.16	3.14	3.15	0.01	0.3
12/6/91	12:35 PM	3.13	3.15	3.13	3.11	3.13	3.13	0.01	0.6
12/6/91	1:10 PM	3.12	3.11	3.14	3.14	3.14	3.12	0.01	0.5
12/6/91	2:10 PM	3.12	3.12	3.13	3.13	3.11	3.12	0.01	0.3
12/6/91	3:35 PM	3.13	3.13	3.13	3.15	3.13	3.13	0.01	0.3
12/7/91	7:50 AM	3.15	3.15	3.14	3.13	3.15	3.14	0.01	0.3
12/7/91	8:50 AM	3.13	3.12	3.12	3.14	3.12	3.13	0.01	0.3
12/7/91	9:50 AM	3.12	3.12	3.13	3.13	3.14	3.13	0.01	0.3
12/7/91	11:35 AM	3.14	3.09	3.13	3.13	3.13	3.12	0.02	0.6

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
12/2/91	10:00 AM	3.13	3.11	3.10	3.10	3.14	3.12	0.02	0.6
12/2/91	11:00 AM	3.12	3.14	3.11	3.13	3.11	3.12	0.01	0.4
12/2/91	12:00 PM	3.11	3.11	3.13	3.10	3.10	3.11	0.01	0.4
12/2/91	1:00 PM	3.15	3.18	3.14	3.19	3.16	3.16	0.02	0.7
12/2/91	2:05 PM	3.12	3.12	3.11	3.12	3.16	3.13	0.02	0.6
12/2/91	3:40 PM	3.10	3.07	3.08	3.08	3.08	3.08	0.01	0.4
12/3/91	7:20 AM	3.14	3.18	3.17	3.19	3.16	3.17	0.02	0.6
12/3/91	8:20 AM	3.17	3.17	3.20	3.19	3.17	3.18	0.01	0.4
12/3/91	9:20 AM	3.15	3.17	3.16	3.16	3.19	3.16	0.01	0.4
12/3/91	10:20 AM	3.14	3.15	3.16	3.19	3.14	3.14	0.01	0.4
12/3/91	11:35 AM	3.15	3.18	3.17	3.16	3.13	3.16	0.02	0.6
12/3/91	12:35 PM	3.11	3.15	3.15	3.15	3.16	3.14	0.02	0.6
12/3/91	1:35 PM	3.15	3.16	3.12	3.19	3.12	3.14	0.02	0.6
12/3/91	2:35 PM	3.14	3.13	3.13	3.13	3.12	3.13	0.01	0.2
12/5/91	7:55 AM	3.17	3.17	3.15	3.14	3.13	3.16	0.02	0.5
12/5/91	8:55 AM	3.14	3.16	3.17	3.15	3.15	3.15	0.01	0.4
12/5/91	9:55 AM	3.10	3.12	3.14	3.12	3.10	3.12	0.02	0.5
12/5/91	11:00 AM	3.15	3.14	3.17	3.15	3.16	3.15	0.01	0.4
12/5/91	11:50 AM	3.15	3.12	3.14	3.12	3.14	3.13	0.01	0.4
12/5/91	12:50 PM	3.15	3.15	3.13	3.13	3.12	3.14	0.01	0.4
12/5/91	1:50 PM	3.15	3.14	3.18	3.15	3.11	3.15	0.03	0.8
12/5/91	2:50 PM	3.13	3.16	3.13	3.11	3.12	3.13	0.02	0.6
12/5/91	3:50 PM	3.14	3.15	3.13	3.15	3.13	3.14	0.01	0.3
12/5/91	4:50 PM	3.14	3.14	3.12	3.16	3.13	3.14	0.01	0.5
12/5/91	5:30 PM	3.11	3.13	3.11	3.13	3.15	3.13	0.02	0.5
12/6/91	7:50 AM	3.13	3.13	3.12	3.13	3.14	3.13	0.01	0.2
12/6/91	9:35 AM	3.10	3.10	3.12	3.13	3.10	3.11	0.01	0.5
12/6/91	10:35 AM	3.12	3.12	3.06	3.09	3.12	3.10	0.02	0.9
12/6/91	11:35 AM	3.12	3.10	3.10	3.11	3.12	3.11	0.01	0.3
12/6/91	12:35 PM	3.10	3.11	3.11	3.11	3.13	3.11	0.01	0.4
12/6/91	1:10 PM	3.16	3.13	3.12	3.12	3.11	3.13	0.02	0.6
12/6/91	2:10 PM	3.11	3.11	3.10	3.11	3.13	3.11	0.01	0.4
12/6/91	3:35 PM	3.11	3.15	3.15	3.11	3.09	3.13	0.03	1.0
12/7/91	7:50 AM	3.13	3.12	3.14	3.14	3.11	3.13	0.01	0.4
12/7/91	8:50 AM	3.11	3.13	3.12	3.14	3.13	3.13	0.01	0.4
12/7/91	9:50 AM	3.12	3.12	3.13	3.12	3.10	3.12	0.01	0.4
12/7/91	11:35 AM	3.12	3.17	3.13	3.10	3.15	3.13	0.03	0.9

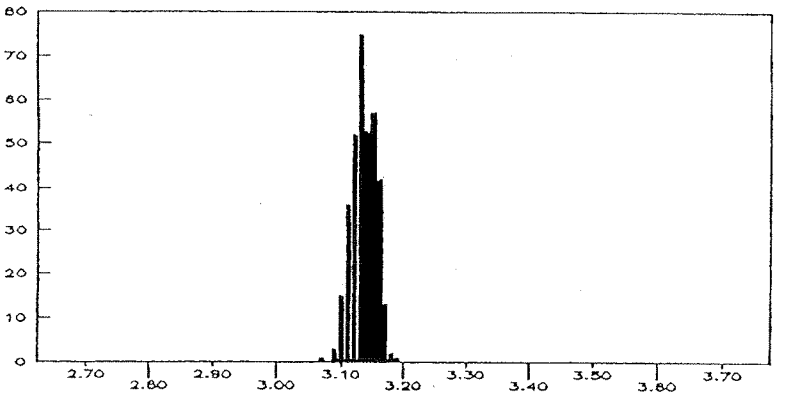
DIGOXIN TABLETS, 0.25 mg

Batch # 4330A – Thickness (mm)



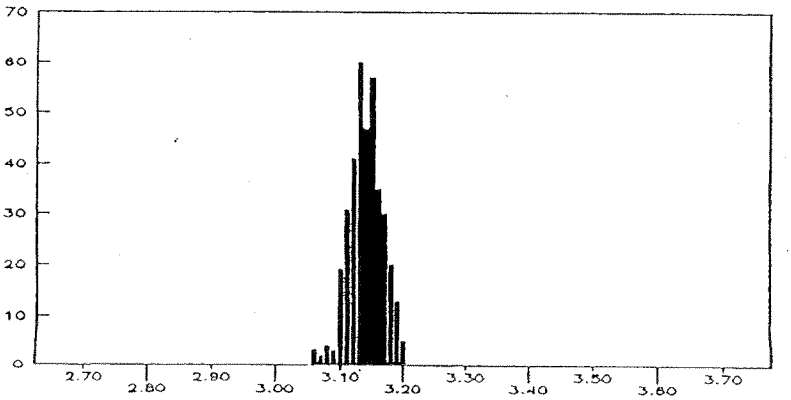
DIGOXIN TABLETS, 0.25 mg

Batch # 4338A – Thickness (mm)



DIGOXIN TABLETS, 0.25 mg

Batch # 4337A – Thickness (mm)



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Compression - Friability (%)

Batch #	4330A	4330A	4336A	4336A	4337A	4337A
Side	Front	Rear	Front	Rear	Front	Rear
1st Third	0.1	0.1	0.1	0.1	0.1	0.2
2nd Third	0.1	0.1	0.2	0.1	0.1	0.1
Final Third	0.1	0.1	0.1	0.1	0.1	0.2
Average	0.1	0.1	0.1	0.1	0.1	0.2
St Dev.	0.0	0.0	0.1	0.0	0.0	0.1
RSD	0.0	0.0	43.3	0.0	0.0	34.6

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Compression - Disintergration (min.)

Batch #	4330A	4330A	4336A	4336A	4337A	4337A
Side	Front	Rear	Front	Rear	Front	Rear
1st Third	2	2	3	2	3	3
2nd Third	3	3	4	3	3	2
Final Third	3	3	2	3	2	4
Average	2.7	2.7	3.0	2.7	2.7	3.0
St Dev.	0.6	0.6	1.0	0.6	0.6	1.0
RSD	21.7	21.7	33.3	21.7	21.7	33.3

MIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Compression - Content Uniformity (%)

Batch #	4330A	4330A	4336A	4336A	4337A	4337A
Side	Front	Rear	Front	Rear	Front	Rear
1	101.7	99.8	102.7	98.5	98.9	103.1
2	100.4	99.9	102.8	98.9	98.6	100.5
3	98.2	99.9	100.8	99.0	97.9	102.2
4	99.8	103.1	104.4	99.0	100.1	99.5
5	100.5	99.9	100.4	100.1	99.3	102.9
6	102.1	101.5	101.3	98.7	102.1	98.4
7	101.1	99.1	99.0	97.7	99.7	99.8
8	100.2	100.5	101.2	99.0	101.3	100.5
9	103.6	100.0	101.4	99.7	100.9	101.3
10	100.8	98.8	99.7	105.4	99.2	97.4
11	100.8	99.8	101.7	98.0	99.9	98.1
12	100.8	98.3	101.0	98.7	102.3	98.3
13	102.3	97.7	99.6	98.4	101.9	97.2
14	101.6	99.0	99.1	99.9	101.2	97.4
15	101.2	101.0	100.9	98.7	100.4	96.8
16	99.9	101.3	101.2	100.5	101.0	98.0
17	101.0	99.8	100.9	98.5	98.6	99.9
18	102.7	101.3	99.4	98.0	98.9	101.1
19	102.0	99.0	101.4	99.3	99.9	100.3
20	103.1	99.0	101.1	100.0	100.1	100.4
21	100.8	101.4	100.2	98.8	99.6	101.0
22	103.9	100.3	97.2	99.1	100.1	100.8
23	99.5	98.8	98.7	97.2	99.6	97.0
24	99.3	101.2	98.6	97.8	99.2	98.6
25	97.7	100.4	99.5	99.0	101.1	104.5
26	100.5	101.5	98.8	100.4	101.9	102.5
27	102.8	101.4	100.0	98.2	99.3	99.9
28	103.2	100.2	99.1	100.1	101.6	105.2
29	100.9	100.9	101.0	100.0	100.8	102.8
30	100.8	100.9	101.0	99.3	100.6	101.3
31	99.7	101.6	100.0	99.6	101.6	103.4
32	97.8	100.6	100.3	99.4	101.2	102.3
33	98.4	100.9	98.9	98.1	100.6	101.8
34	102.4	101.7	98.7	97.7	101.1	100.9
35	100.8	99.9	100.6	100.2	100.0	103.0
36	100.2	100.8			99.0	104.5
37					99.7	102.4
Average	100.9	100.3	100.4	99.2	100.2	100.7
Dev.	1.6	1.1	1.4	1.4	1.1	2.3
RSD	1.5	1.1	1.4	1.4	1.1	2.3

IIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

Compression - Dissolution (%) - 15 min.

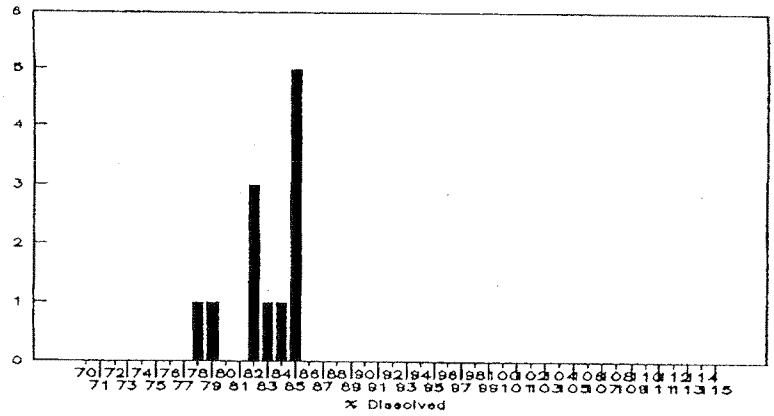
Batch #	4330A	4330A	4330A	4336A	4336A	4336A	4337A	4337A	4337A
Sample	1st Third	2nd Third	Final Third	1st Third	2nd Third	Final Third	1st Third	2nd Third	Final Third
1	78.9	81.5	81.0	75.3	78.8	82.7	84.0	83.4	82.3
2	84.8	84.4	81.0	73.2	77.7	81.1	84.5	83.6	84.0
3	81.1	82.3	80.5	73.7	79.6	79.2	81.2	83.0	82.2
4	81.5	79.9	81.7	71.6	76.9	79.5	83.4	83.2	78.5
5	84.9	81.6	83.6	73.7	77.4	79.8	79.6	82.1	78.3
6	82.9	81.8	81.8	71.3	77.3	81.2	82.3	82.4	80.3
7	77.2	79.5	81.6	73.6	73.8	78.4	79.9	83.4	78.9
8	84.1	77.8	83.8	74.3	77.5	80.0	81.4	83.7	78.3
9	84.9	81.3	81.9	73.5	80.0	82.1	82.5	82.8	78.1
10	84.1	80.8	81.7	73.1	80.8	80.3	79.9	83.0	80.1
11	81.7	82.4	84.9	72.7	79.3	83.2	81.0	84.2	78.2
12	83.4	82.5	82.8	73.2	80.8	81.2	80.5	82.5	79.7
Average	82.5	81.3	82.2	73.3	78.3	80.7	81.7	83.1	79.9
St Dev.	2.5	1.7	1.3	1.1	2.0	1.5	1.7	0.6	2.0
RSD	3.0	2.1	1.6	1.5	2.5	1.8	2.0	0.7	2.5

Compression - Dissolution (%) - 60 min.

Batch #	4330A	4330A	4330A	4336A	4336A	4336A	4337A	4337A	4337A
Sample	1st Third	2nd Third	Final Third	1st Third	2nd Third	Final Third	1st Third	2nd Third	Final Third
1	90.0	94.4	96.6	89.5	89.8	92.4	104.7	94.7	91.4
2	94.2	94.1	96.7	93.2	90.7	97.5	98.1	99.1	94.9
3	94.8	94.9	100.7	91.8	93.2	94.8	93.6	100.9	93.7
4	95.6	94.5	99.1	89.7	89.3	99.9	94.9	98.6	92.1
5	97.2	95.3	97.2	91.2	92.0	98.5	93.5	100.7	92.6
6	95.9	94.8	102.0	88.5	96.1	107.5	92.2	100.0	90.1
7	94.4	96.1	98.7	89.6	87.2	95.6	101.6	101.3	90.4
8	96.1	95.2	95.5	90.4	89.5	93.8	96.1	99.5	88.8
9	97.4	98.7	89.4	91.9	97.9	94.7	102.8	99.7	89.7
10	96.6	93.6	102.5	91.9	93.2	97.0	98.6	99.1	92.5
11	94.5	93.0	93.1	92.9	90.9	96.6	95.2	102.5	89.6
12	97.2	99.0	101.7	96.1	92.3	96.3	96.5	100.3	88.1
Average	95.3	95.3	97.8	91.4	91.8	97.1	97.3	99.7	91.2
St Dev.	2.0	1.8	3.9	2.1	3.0	3.9	4.0	1.9	2.1
RSD	2.1	1.9	4.0	2.3	3.3	4.0	4.1	1.9	2.3

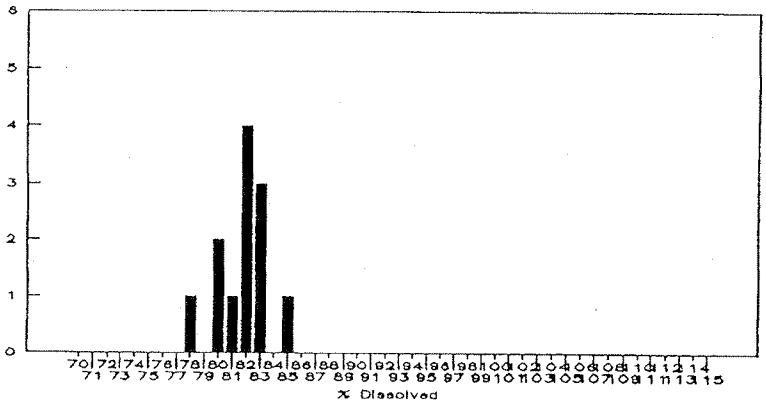
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

15 Min. Dissolution — 1st Third



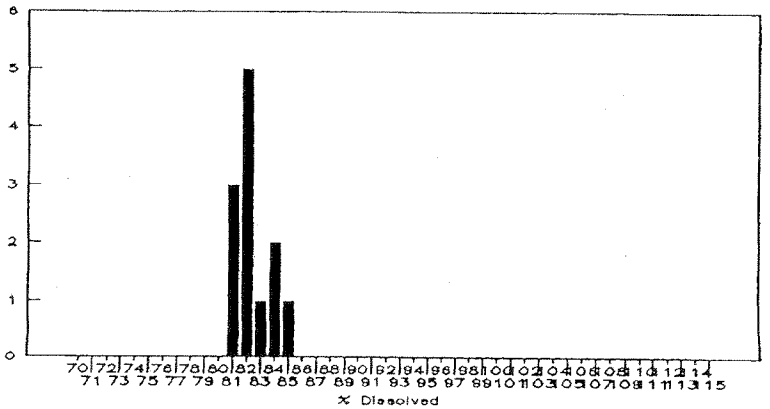
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

15 Min. Dissolution — 2nd Third



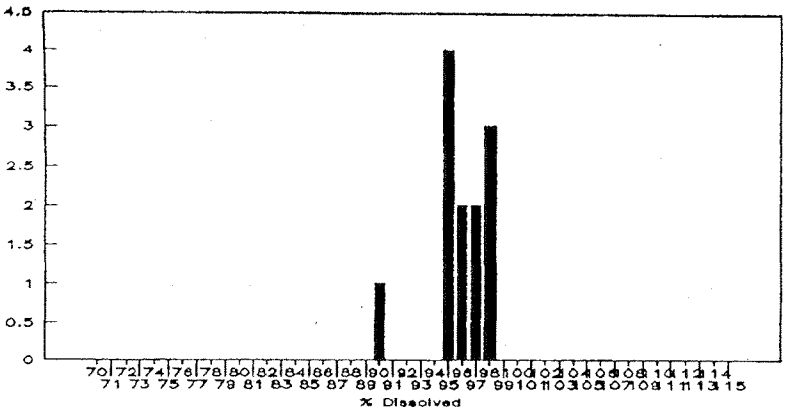
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

15 Min. Dissolution — Final Third



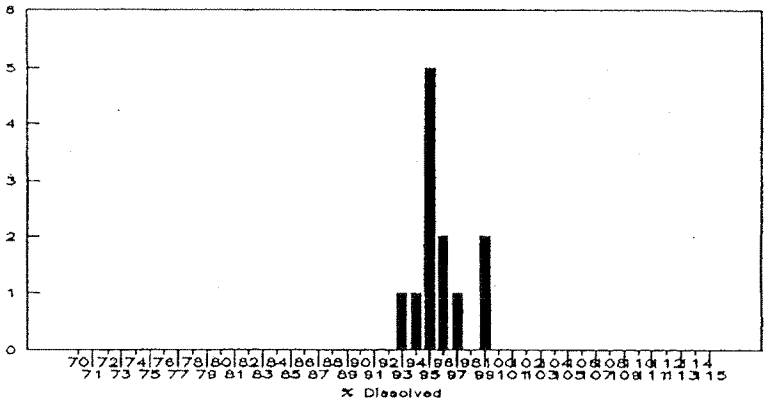
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

60 Min. Dissolution — 1st Third



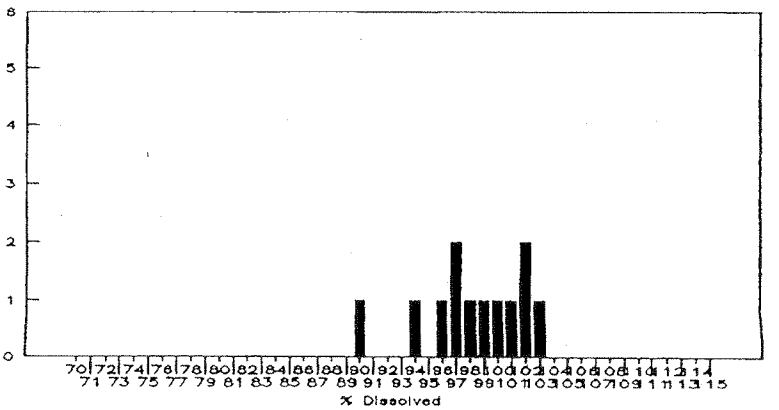
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

60 Min. Dissolution — 2nd Third



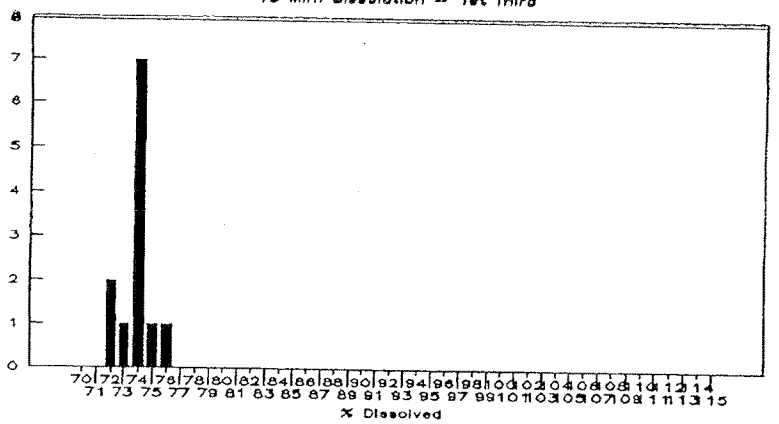
DIGOXIN TABLETS, 0.25 mg — BATCH 4330A

60 Min. Dissolution — Final Third



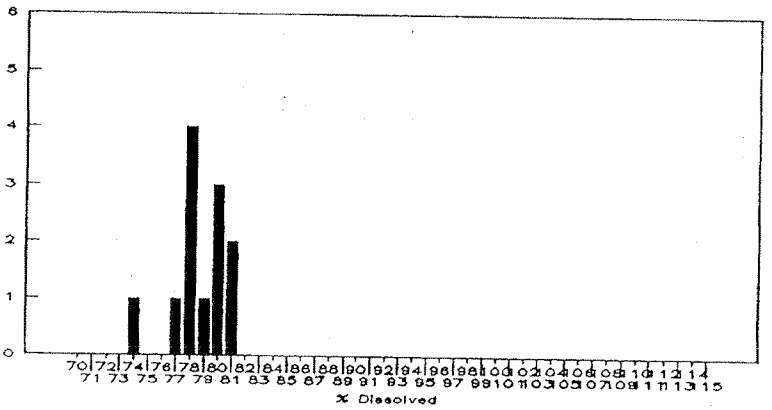
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

15 Min. Dissolution — 1st Third



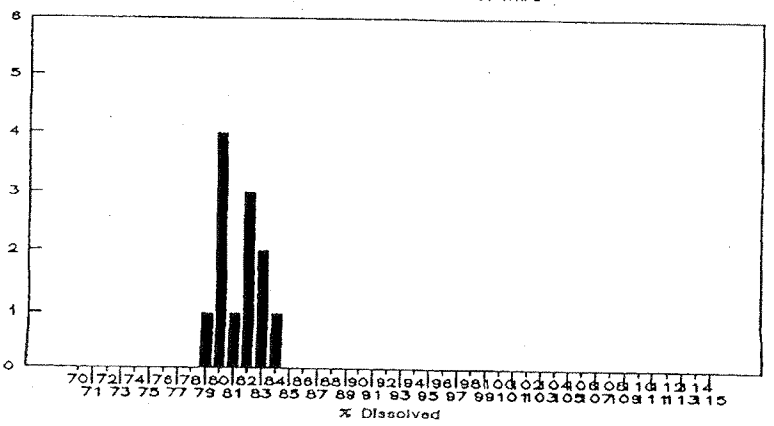
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

15 Min. Dissolution — 2nd Third



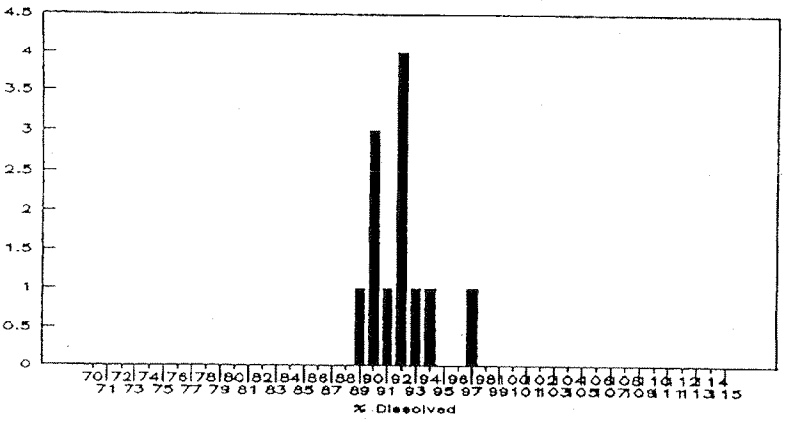
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

15 Min. Dissolution — Final Third



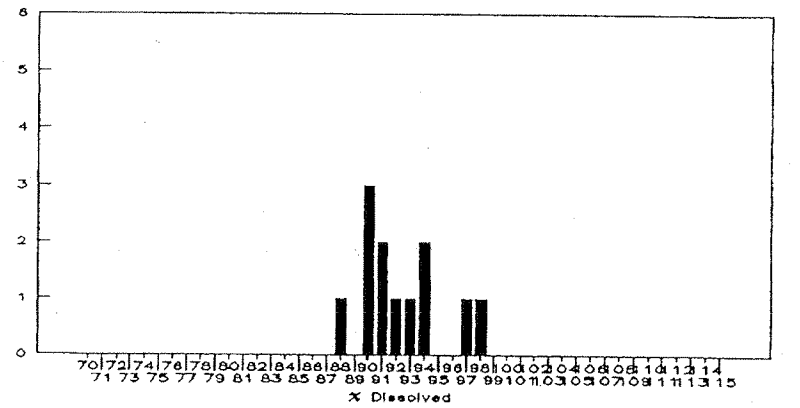
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

60 Min. Dissolution — 1st Third



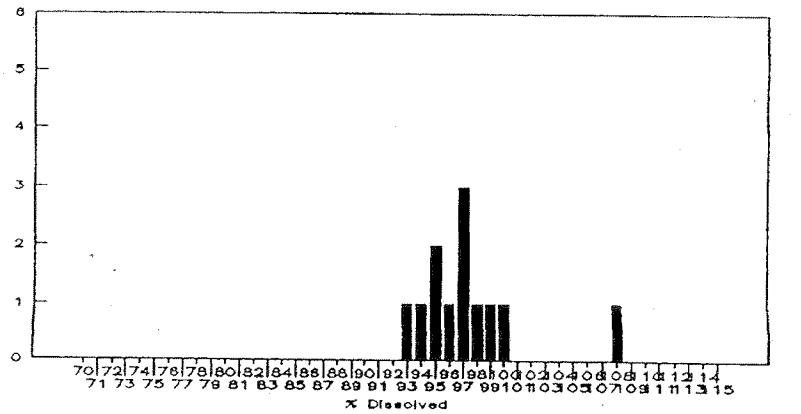
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

60 Min. Dissolution — 2nd Third



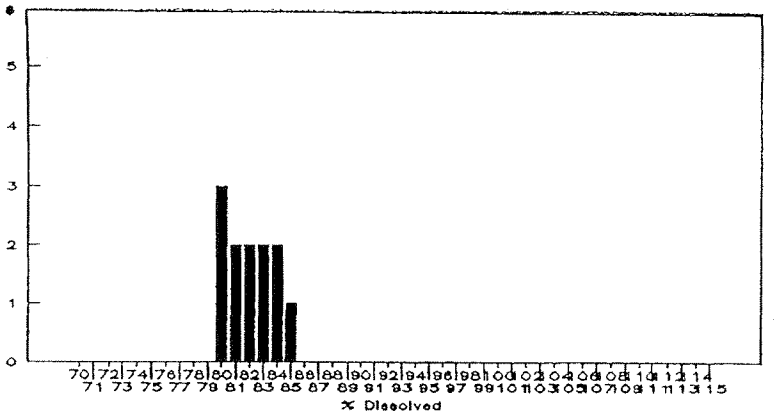
DIGOXIN TABLETS, 0.25 mg — BATCH 4336A

60 Min. Dissolution — Final Third



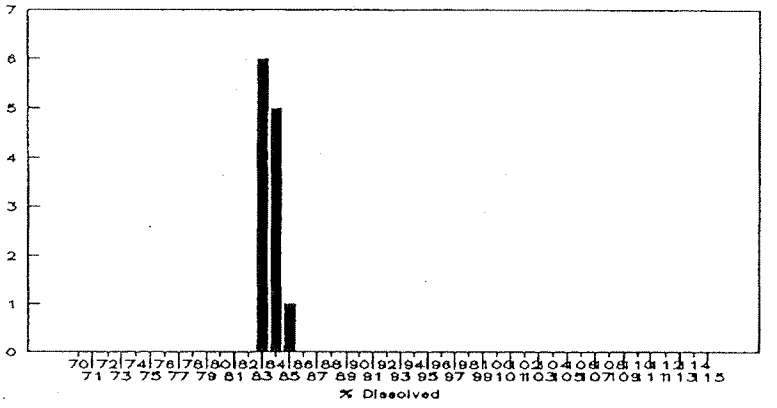
DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

15 Min. Dissolution — 1st Third



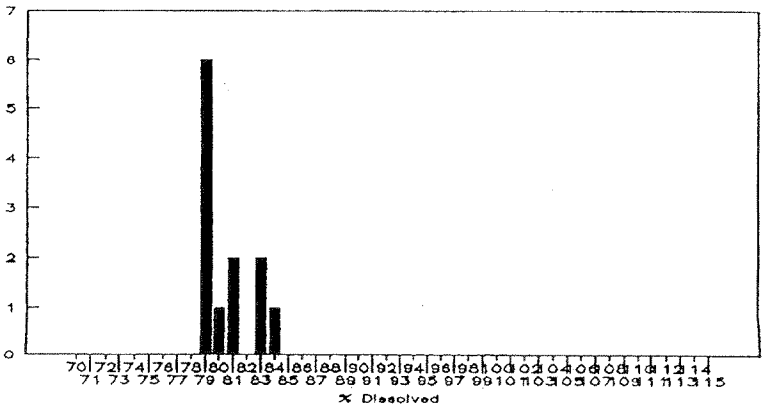
DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

15 Min. Dissolution — 2nd Third



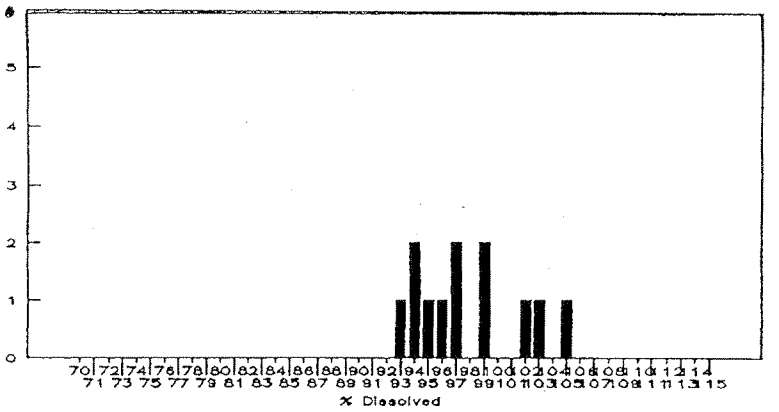
DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

15 Min. Dissolution — Final Third



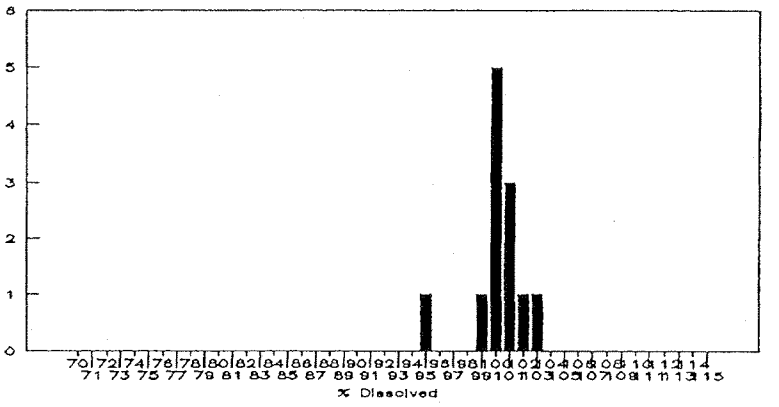
DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

60 Min. Dissolution — 1st Third



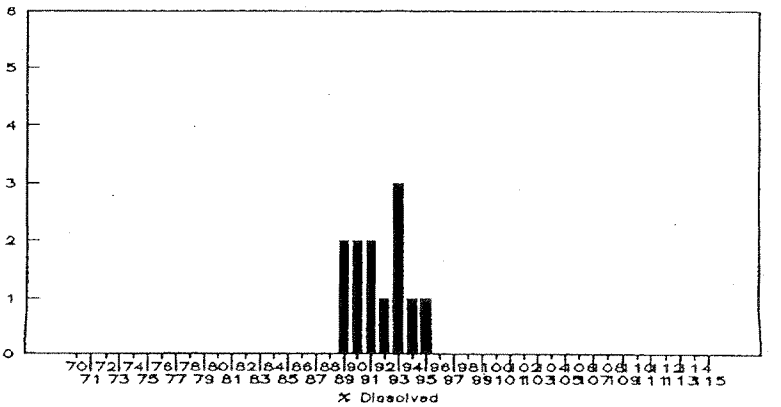
DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

60 Min. Dissolution — 2nd Third



DIGOXIN TABLETS, 0.25 mg — BATCH 4337A

60 Min. Dissolution — Final Third



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

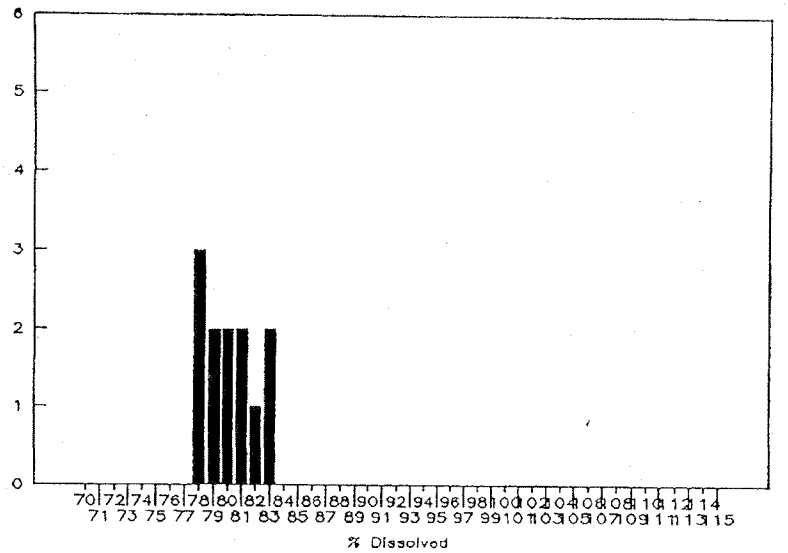
DIGOXIN TABLETS, 0.25 mg

Compression - Composite Dissolution (%)

Batch #	4330A	4330A	4336A	4336A	4337A	4337A
Time	15 min.	60 min.	15 min.	60 min.	15 min.	60 min.
1	78.7	91.2	81.3	91.1	79.8	91.8
2	80.1	92.0	81.3	94.7	73.6	89.4
3	81.9	91.0	82.0	97.9	75.6	90.4
4	79.8	91.6	81.5	95.7	75.2	89.1
5	77.9	91.9	80.7	93.9	80.0	97.5
6	80.1	93.2	81.0	93.0	63.8	98.1
7	77.7	92.0	79.1	93.9	73.2	89.8
8	78.0	92.1	82.1	92.7	75.4	92.5
9	78.5	92.0	80.3	91.7	78.6	91.7
10	82.4	96.7	80.8	96.5	75.7	91.9
11	82.2	92.0	80.8	94.8	65.1	90.5
12	79.7	93.7	80.3	93.3	70.5	93.3
Average	79.8	92.5	80.9	94.1	73.9	92.2
St Dev.	1.7	1.5	0.8	2.0	5.2	2.9
RSD	2.1	1.7	1.0	2.1	7.0	3.2

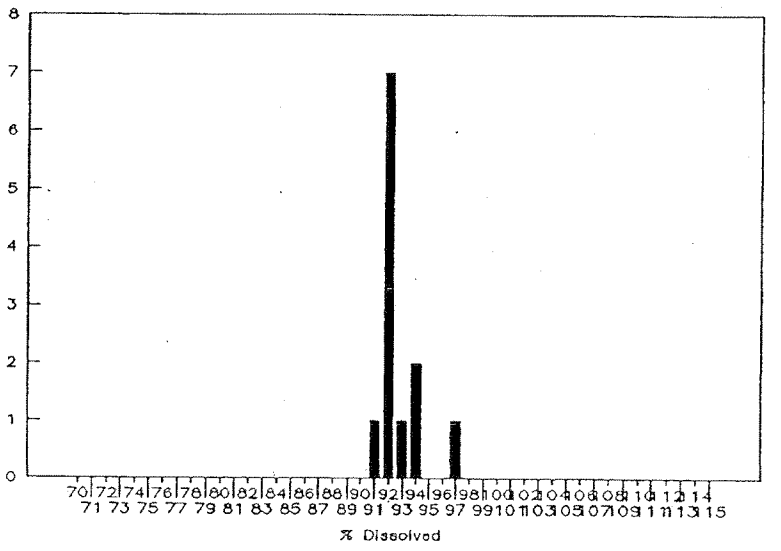
DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

Composite Dissolution – 15 Min.



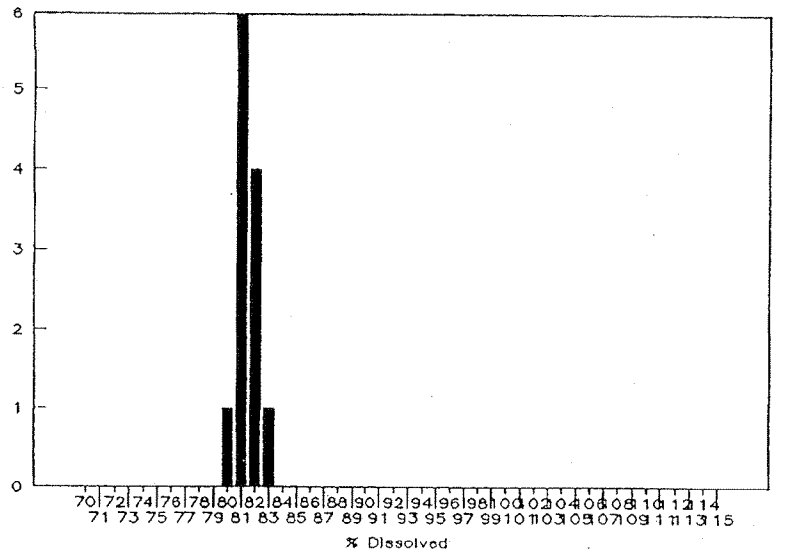
DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

Composite Dissolution – 60 Min.



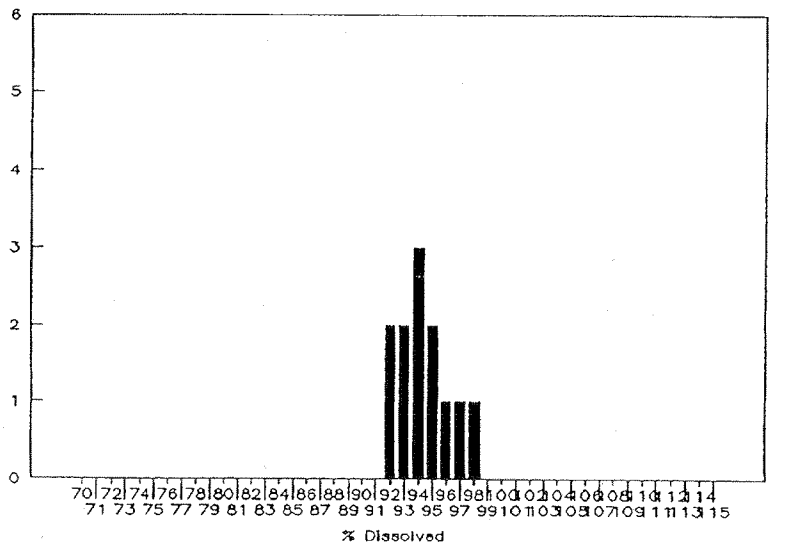
DIGOXIN TABLETS, 0.25 mg – BATCH 4336A

Composite Dissolution – 15 Min.



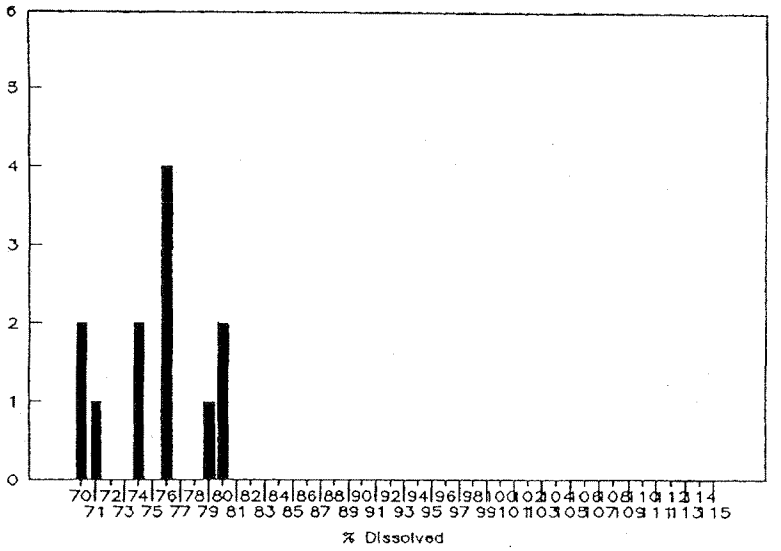
DIGOXIN TABLETS, 0.25 mg – BATCH 4336A

Composite Dissolution – 60 Min.



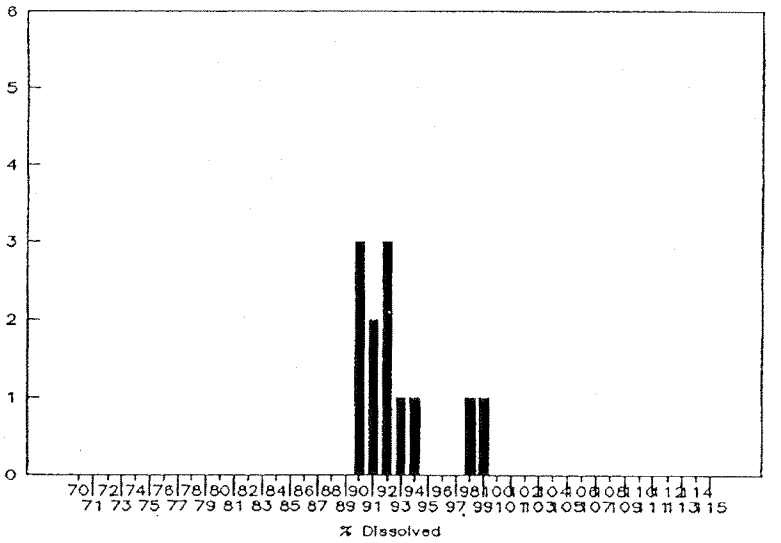
DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

Composite Dissolution – 15 Min.



DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

Composite Dissolution – 60 Min.



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.25 mg

High/Low kp - Dissolution (%) - 15 min.

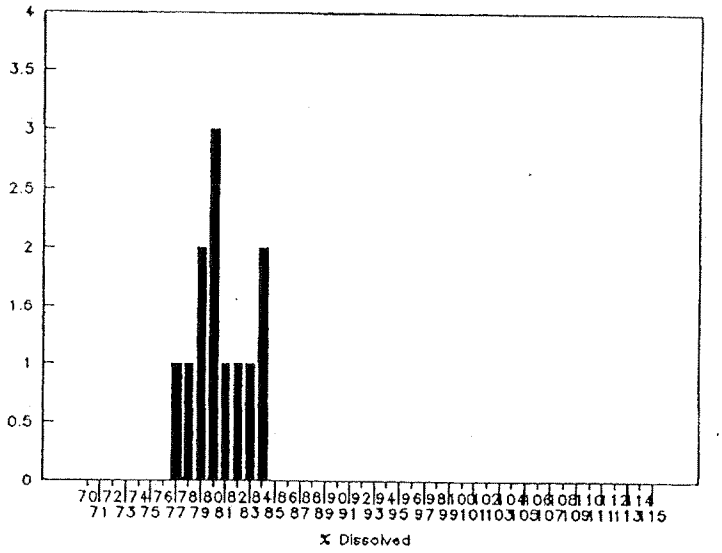
Batch #	4330A	4330A	4330A	4330A	4336A	4336A	4336A	4336A	4337A	4337A	4337A	4337A
Sample	High kp	High kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp
Side	Front	Rear	Front	Rear	Front	Rear	Front	Rear	Front	Rear	Front	Rear
1	78.4	80.0	80.0	81.3	82.6	81.1	82.4	78.1	77.0	77.1	80.6	79.5
2	81.2	80.2	78.3	78.6	81.3	77.6	82.1	80.2	77.7	77.8	82.3	81.2
3	82.8	79.6	80.6	76.9	79.5	82.0	80.9	81.4	78.4	78.8	79.3	79.6
4	83.6	79.3	78.3	79.1	78.8	78.7	83.1	77.7	80.8	81.0	80.1	81.5
5	83.4	76.7	80.5	77.5	80.7	80.7	81.2	80.1	79.1	81.2	80.8	80.9
6	77.9	79.0	79.3	79.8	82.7	81.1	83.1	81.4	80.7	79.2	81.0	81.0
Average	81.2	79.1	79.5	78.9	80.9	80.2	82.1	79.8	79.0	79.2	80.7	80.6
St Dev.	2.5	1.3	1.0	1.6	1.6	1.7	0.9	1.6	1.6	1.7	1.0	0.9
RSD	3.1	1.6	1.3	2.0	2.0	2.1	1.1	2.0	2.0	2.1	1.2	1.1

High/Low kp - Dissolution (%) - 60 min.

Batch #	4330A	4330A	4330A	4330A	4336A	4336A	4336A	4336A	4337A	4337A	4337A	4337A
Sample	High kp	High kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp
Side	Front	Rear	Front	Rear	Front	Rear	Front	Rear	Front	Rear	Front	Rear
1	88.6	89.6	88.3	98.7	92.8	96.0	94.2	97.4	91.2	94.2	90.6	97.7
2	89.7	89.7	90.2	91.6	93.2	96.1	96.9	95.1	92.1	93.0	100.5	98.0
3	95.2	88.5	89.4	91.1	94.6	96.4	101.5	97.8	92.7	92.5	93.4	95.8
4	93.9	89.7	91.3	90.5	94.3	98.7	95.9	95.0	92.2	94.7	94.7	97.2
5	91.0	93.2	83.6	90.8	95.0	98.0	97.7	97.7	92.8	94.9	96.6	98.0
6	89.7	92.6	88.1	92.2	95.4	95.2	94.7	95.3	93.1	94.0	95.1	95.3
Average	91.4	90.6	88.5	92.5	94.2	96.7	96.8	96.4	92.4	93.9	95.2	97.0
St Dev.	2.6	1.9	2.7	3.1	1.0	1.3	2.6	1.4	0.7	0.9	3.3	1.2
RSD	2.9	2.1	3.0	3.4	1.1	1.4	2.7	1.4	0.7	1.0	3.5	1.2

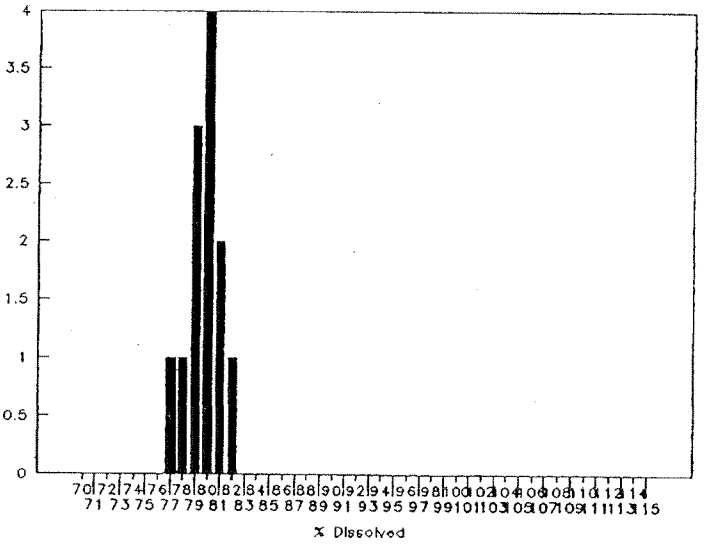
DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

15 Min. Dissolution – High kp



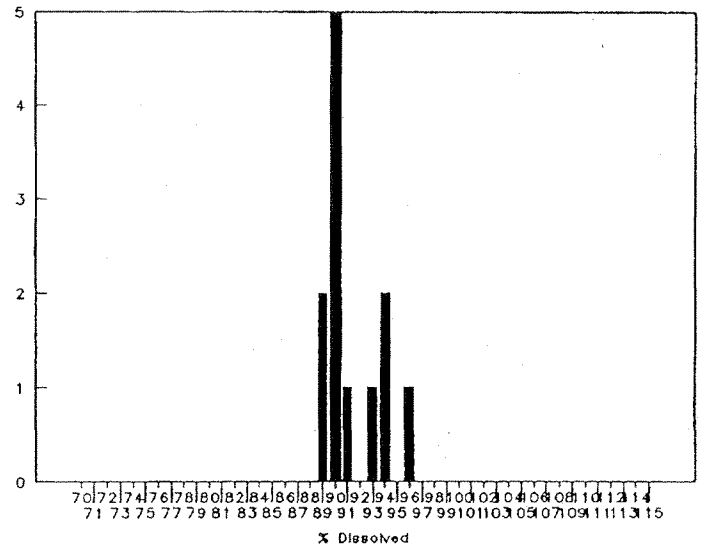
DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

15 Min. Dissolution – Low kp



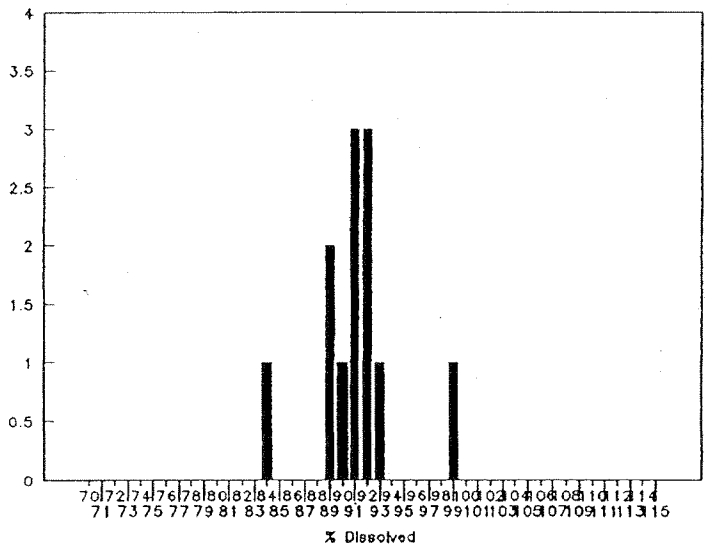
DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

60 Min. Dissolution – High kp

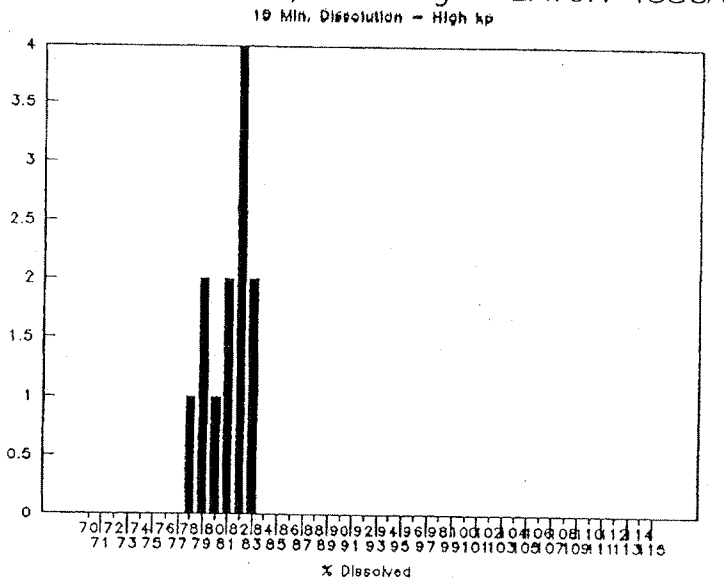


DIGOXIN TABLETS, 0.25 mg – BATCH 4330A

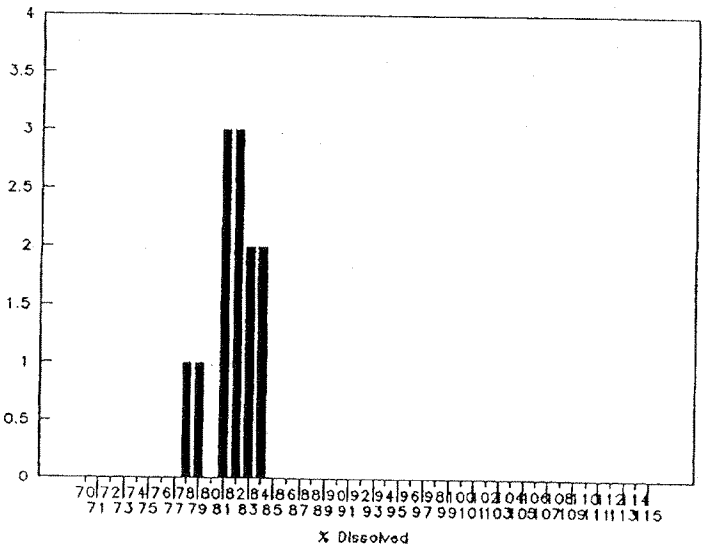
60 Min. Dissolution – Low kp



DIGOXIN TABLETS, 0.25 mg – BATCH 4336A

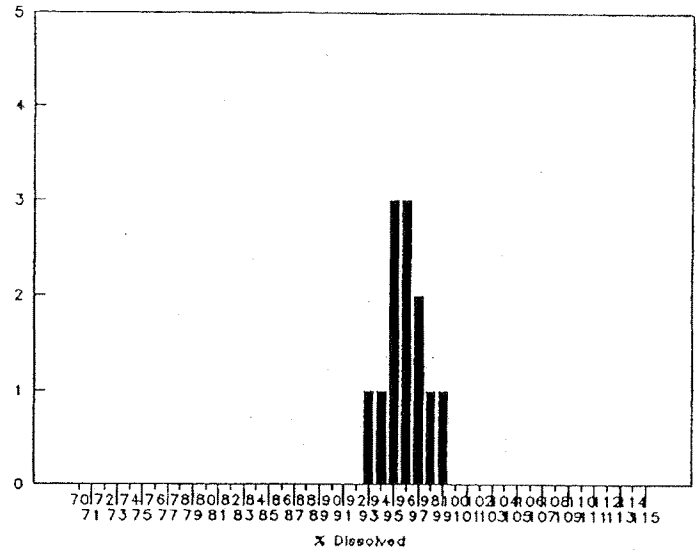


DIGOXIN TABLETS, 0.25 mg – BATCH 4336A



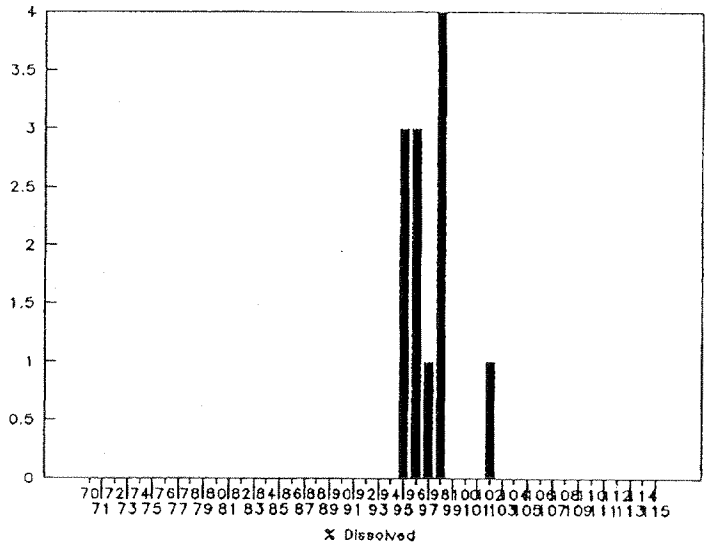
DIGOXIN TABLETS, 0.25 mg – BATCH 4336A

60 Min. Dissolution – High kp



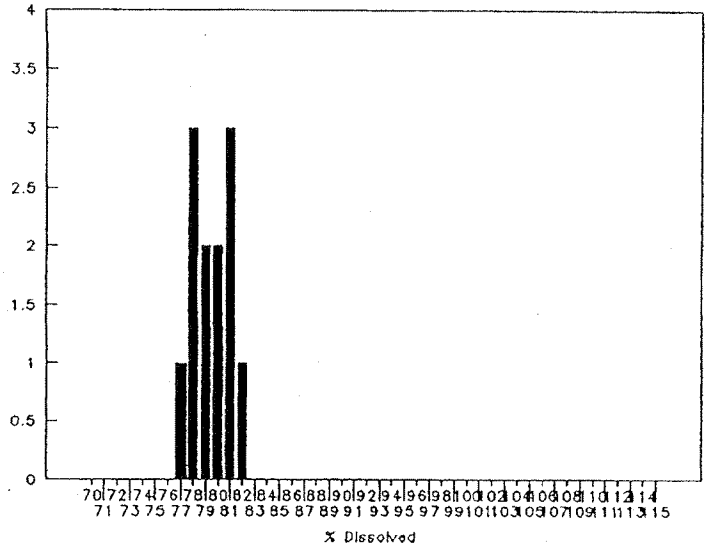
DIGOXIN TABLETS, 0.25 mg – BATCH 4336A

60 Min. Dissolution – Low kp



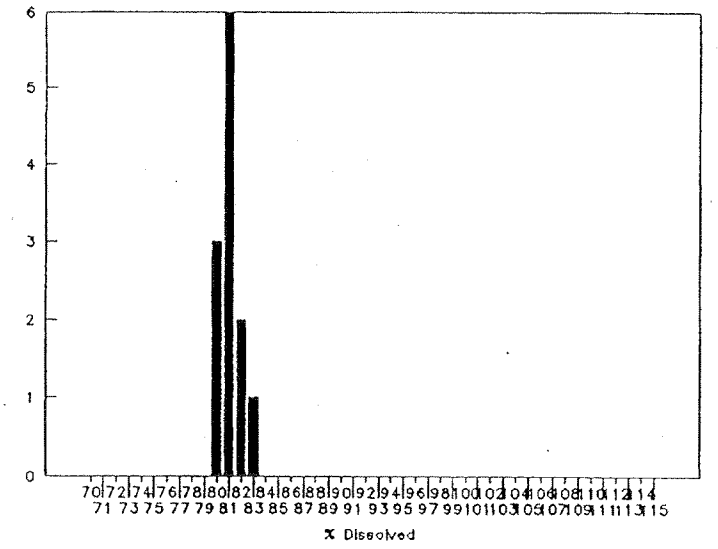
DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

15 Min. Dissolution – High kp



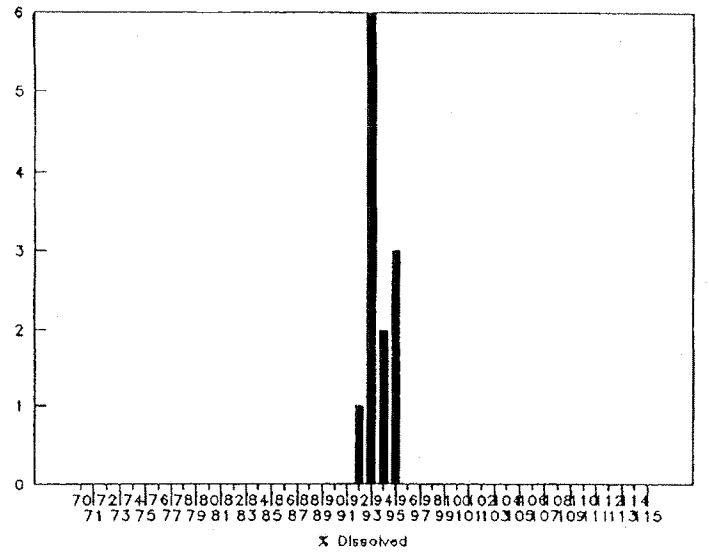
DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

15 Min. Dissolution – Low kp



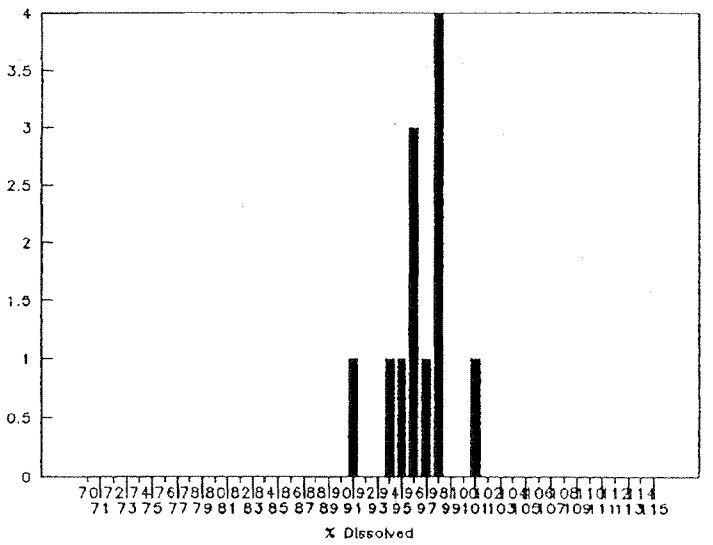
DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

60 Min. Dissolution – High kp



DIGOXIN TABLETS, 0.25 mg – BATCH 4337A

60 Min. Dissolution – Low kp



Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.25 mg (146)

BATCH #: 4330A TABLET PRESS ID #: 66

	Limit	Time
High KP	above 8.0 lcP	8.04 Am
Low KP	1.0 - 3.0 lcP	8.40 Am
Maximum KP	Not Possible	—
Regular Speed	22 RPM	—

	RPM	Time
High Speed	26	9.20 Am
Low Speed	18	9.58 Am

Done By: MB Date: 11-29-94

FD301.1

Amide Pharmaceutical, Inc. Process Validation

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4330A Date: 11.29.94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : ~~2.0 - 8.0 KP~~ 11/17/94 JJ

High KP. Above 8.0.

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
8-03 AM 1-Min.	1.210	3.08	3.05	3.09	6.6	7.0	7.5	MS
8.07 AM 5-Min.	1.209	3.07	3.06	3.08	7.1	6.7	7.1	MS

Rear Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
1-Min.	1.211	3.06	3.07	3.08	7.0	6.1	6.7	MS
5-Min.	1.209	3.07	3.08	3.06	7.3	7.0	6.8	MS

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet (mg)									
1-Min.	121	121	120	120	120	119	120	120	120	123
5-Min.	120	121	119	118	121	119	122	121	122	119

Rear Exit Chute										
Time	Weight of Each Tablet (mg)									
1-Min.	119	123	121	120	120	121	122	121	119	121
5-Min.	120	119	121	118	120	120	119	121	121	120

Comments: Higher Hardness Tablet not possible. Tablets running at upper limit of 6->7. JJ 11/29/94

Amide Pharmaceutical, Inc. Process Validation

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4330A Date: 11-29-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits ~~: 2.0 - 8.0 KP~~ 11/17/94
hard KP 1.0 - 3.0

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
8:39 AM 1 Min.	1.192	3.32	3.33	3.32	2.0	1.9	1.9	MS
8:43 AM 5 Min.	1.206	3.31	3.32	3.33	2.0	2.1	2.5	MS

Rear Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
1 Min.	1.199	3.32	3.34	3.35	1.8	1.7	1.8	MS
5 Min.	1.200	3.34	3.34	3.33	1.7	1.9	1.8	MS

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet (mg)									
1 Min.	118	118	118	121	118	119	120	119	121	119
5 Min.	122	121	122	122	119	120	119	119	121	117

Rear Exit Chute										
Time	Weight of Each Tablet (mg)									
1 Min.	118	120	119	120	120	120	119	121	119	120
5 Min.	122	121	120	119	119	120	120	118	119	119

Comments:

<PD187.1>

Amide Pharmaceutical, Inc. Process Validation

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4330A Date: 11-29-94

Tablet Press Id: 66 Hardness Tester Id: 257 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 – 3.7 mm
Hardness Limits : 2.0 – 8.0 KP

High Speed RPM 26

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
9:19 AM 1 Min.	1.200	3.15	3.16	3.14	4.8	4.7	4.3	MB
9:23 AM 5 Min.	1.195	3.11	3.14	3.12	4.3	3.9	5.0	MB

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.196	3.09	3.03	3.07	3.7	4.1	4.4	MB
5 Min.	1.197	3.15	3.11	3.13	4.3	4.2	4.2	MB

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet (mg)									
1 Min.	121	122	118	117	122	120	119	118	123	122
5 Min.	116	123	117	120	119	121	120	119	118	114

Rear Exit Chute										
Time	Weight of Each Tablet (mg)									
1 Min.	116	119	120	118	118	118	121	120	119	117
5 Min.	121	120	121	117	122	123	120	122	120	119

Comments:

<P0187.1>

Amide Pharmaceutical, Inc. Process Validation Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4330A Date: 11-29-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : 2.0 - 8.0 KP

Lowsbed RPM 18

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
9:57 AM 1 Min.	1.206	3.12	3.15	3.14	5.5	4.8	5.0	MS
10:01 AM 5 Min.	1.209	3.13	3.15	3.14	5.4	4.4	5.3	MS

Rear Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
1 Min.	1.209	3.13	3.14	3.13	4.8	4.5	5.1	MS
5 Min.	1.208	3.12	3.15	3.14	5.7	5.6	5.5	MS

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	120	122	121	123	121	123	119	120	124
5 Min.	119	120	121	119	121	122	121	117	122	125

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	121	120	120	121	122	120	119	120	121	121
5 Min.	121	121	122	121	120	123	120	122	119	120

Comments:

<P0187.1>

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.25mg.

BATCH #: 4336 A

TABLET PRESS ID #: 66

	Limit	Time
High KP	above 8.0 kp	2.55 Pm
Low KP	1.0 – 3.0 kp.	3.15 Pm
Maximum KP	Not Possible	—
Regular Speed	23	—

	RPM	Time
High Speed	27 Rpm	3.35 Pm
Low Speed	19	4.00 Pm

Done By:	P.K	Date:	12-1-94

PD301.1

Amide Pharmaceutical, Inc. — **Process Validation** — Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4336A Date: 12/1/94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 251

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 - 3.7 mm

Hardness Limits : ~~2.0 – 8.0 KP~~ ↺ 11/23/94

High KP Above 8.0 RPM -23

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
2:54 Pm 1 Min.	1.201	3.08	3.10	3.10	6.2	6.5	6.7	M.M.
2:58 Pm 5 Min.	1.198	3.10	3.09	3.10	6.6	6.4	6.1	M.M.

Rear Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
1 Min.	1.201	3.12	3.10	3.11	6.4	6.4	6.6	M.M.
5 Min.	1.199	3.10	3.10	3.08	6.2	6.7	6.2	M.M.

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	118	121	121	118	119	120	119	119	120	117
5 Min.	120	121	120	119	120	118	120	121	118	120

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	120	119	120	119	119	121	120	118	119
5 Min.	116	122	119	121	120	119	119	118	120	119

Comments: Higher hardness not possible JL 12/1/94

Amide Pharmaceutical, Inc. **Process Validation**

COMPRESSION LOG SHEET

Prod Id: 146 Prod Name: **Digoxin Tablets 0.25 mg** Batch #: 4336A Date: 12/1/94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 – 3.7 mm
Hardness Limits : ~~2.0 – 8.0 KP~~ 1.0 – 3.0 KP (JJ 11/30/94)

RPM - 23

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
3:14 Pm 1 Min.	1.193	3.36	3.35	3.35	1.9	1.7	1.9	M.M.
3:18 Pm 5 Min.	1.194	3.34	3.37	3.35	1.9	1.7	2.2	M.M.

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.197	3.35	3.36	3.38	1.9	1.8	1.8	M.M.
5 Min.	1.199	3.36	3.37	3.37	1.7	2.0	1.9	M.M.

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	119	120	117	119	118	121	117	120	118
5 Min.	120	119	118	117	121	120	120	119	121	119

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	119	121	119	117	120	118	121	119	120	120
5 Min.	118	120	118	117	119	117	120	121	119	121

Comments:

Amide Pharmaceutical, Inc. Process Validation

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4336A Date: 12/11/94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 546 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : 2.0 - 8.0 KP

High Speed 27 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
3:34 PM 1 Min.	1.174	3.15	3.15	3.20	4.6	4.2	4.4	KP
3:38 PM 5 Min.	1.184	3.20	3.18	3.12	5.2	4.2	5.2	KP

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.184	3.14	3.14	3.20	5.6	5.1	5.0	KP
5 Min.	1.194	3.16	3.14	3.18	5.4	5.5	5.5	KP

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	116	119	117	120	116	121	117	120	116
5 Min.	120	119	113	118	115	115	117	119	114	119

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	119	119	120	120	120	119	121	117	121	119
5 Min.	119	119	120	119	115	121	109	122	111	117

Comments:

Amide Pharmaceutical, Inc. Process Validation Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4336A Date: 12/11/94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : 2.0 - 8.0 KP

Lowspeed 19 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
3:59 Pm 1 Min.	1.204	3.16	3.19	3.18	5.3	5.2	5.2	KS
4:03 Pm 5 Min.	1.213	3.15	3.18	3.16	5.4	5.3	5.5	KS

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.205	3.12	3.16	3.15	5.2	5.1	5.4	KS
5 Min.	1.200	3.13	3.15	3.14	5.2	5.1	5.2	KS

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	119	122	123	121	123	120	119	120	119	120
5 Min.	123	124	117	118	121	121	120	124	120	121

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	120	116	121	119	119	122	119	120	121
5 Min.	119	120	120	120	119	123	121	117	121	118

Comments:

<PD187.1>

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.25 mg

BATCH #: 4337A

TABLET PRESS ID #: 66

	Limit	Time
High KP	above 8.0 lcP	9.57 Am
Low KP	1.0 - 3.0 lcP	10.28 Am
Maximum KP	Not possible	—
Regular Speed	24	—

	RPM	Time
High Speed	28	10.58 Am
Low Speed	19	11.25 Am

Done By: PC Date: 12-7-94

PD301.1

Amide Pharmaceutical, Inc. — **Process Validation** — Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: **146** Prod Name: **Digoxin Tablets 0.25 mg** Batch #: 4337A Date: 12-7-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 – 3.7 mm
Hardness Limits : ~~2.0 – 8.0 KP~~ ↺ 11/23/94

High KP Above 8.0 RPM - 24

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
9:56 Am 1 Min.	1.189	3.06	3.05	3.10	5.7	6.1	6.4	P.K
10:00 Am 5 Min.	1.198	3.09	3.08	3.05	6.1	5.9	6.0	P.K

Rear Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
1 Min.	1.195	3.11	3.12	3.09	6.0	5.8	6.3	P.K
5 Min.	1.194	3.08	3.10	3.0)	5.4	6.0	6.0	P.K

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	118	120	118	122	119	120	120	119	118	119
5 Min.	119	118	119	120	117	119	120	121	120	121

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	120	119	120	119	121	118	121	117	118	119
5 Min.	119	120	118	121	117	119	118	120	122	118

Comments: high Kp tablets of above 8 Kp cannot be compressed for this batch. Highest hardness obtained was 6.4 Kp AN 12-7-94

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4337A Date: 12-7-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : ~~2.0 - 8.0 KP~~ D 11/23/94

Low KP 1.0 - 3.0 RPM-24

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
10:27 Am 1 Min.	1.191	3.32	3.36	3.34	1.1	1.4	1.3	P.K
10:31 Am 5 Min.	1.199	3.41	3.37	3.40	1.2	1.3	1.5	P.K

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.190	3.31	3.39	3.34	1.5	1.5	1.7	P.K
5 Min.	1.192	3.36	3.35	3.37	1.6	1.5	1.3	P.K

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	121	122	119	120	119	122	118	119	120	120
5 Min.	120	119	121	122	120	120	121	120	118	119

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	122	118	119	119	120	118	121	118	117	119
5 Min.	120	121	120	118	121	120	120	119	118	122

Comments:

<P0187.1>

COMPRESSION DATA SHEET

Prod Id: 146 Prod Name: Digoxin Tablets 0.25 mg Batch #: 4337A Date: 12-7-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 641 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 – 1.224 g

Thickness Limits : 2.7 – 3.7 mm
Hardness Limits : 2.0 – 8.0 KP

High Speed 28 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
10:57 Am 1 Min.	1.210	3.14	3.16	3.15	4.3	4.1	4.6	P.K
11:01 Am 5 Min.	1.206	3.16	3.12	3.18	4.1	4.4	4.0	P.K

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.222	3.22	3.16	3.18	5.4	4.6	5.7	P.K
5 Min.	1.221	3.15	3.18	3.16	4.4	5.3	5.1	P.K

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	119	124	119	126	125	119	117	125	120	119
5 Min.	121	122	120	121	126	124	115	117	122	120

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	123	126	119	124	121	125	118	121	123	120
5 Min.	122	123	118	126	120	123	117	122	119	121

Comments:

Amide Pharmaceutical, Inc. **Process Validation** Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: **146** Prod Name: **Digoxin Tablets 0.25 mg** Batch #: 4337A Date: 12-7-94

Tablet Press Id: 66 Hardness Tester Id: 251 Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 120.0 mg
Target Weight (10 Tablets) : 1.200 g
Weight Range (10 Tablets) : 1.176 - 1.224 g

Thickness Limits : 2.7 - 3.7 mm
Hardness Limits : 2.0 - 8.0 KP

Low Speed 19 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP			Init
11:24 Am 1 Min.	1.208	3.16	3.15	3.16	4.5	4.7	4.8	P.K
11:28 Am 5 Min.	1.206	3.14	3.16	3.15	4.9	4.6	4.4	P.K

Rear Exit Chute								
Time	Weight* (g)	Thicknes mm			Hardness KP			Init
1 Min.	1.208	3.13	3.17	3.12	5.2	4.6	5.5	P.K
5 Min.	1.210	3.12	3.16	3.15	5.1	5.5	4.8	P.K

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	121	122	120	121	119	120	120	121	119	120
5 Min.	120	120	121	120	121	122	120	120	117 ~~116~~ 113	

F.K. 12-7-94

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	122	122	121	120	118	121	123	121	120	122
5 Min.	122	120	120	121	119	120	121	122	119	124

Comments:

<0187.1>

Amide Pharmaceutical, Inc. Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets 0.25 mg

SPECIFICATION: USP CONTROL #: 4330A

CHEMIST: P.K/S.T K.A VOLUME #: 321-04/326.01 PAGE #: 252/31 164 DATE: 12/1/94

SAMPLE STAGE: Overall composite of Batch Dated 11/29/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	White	White
Profile:	Round Bisected Tablets	Round Bisected Tablets
Other: Debossed	"A 146" on bisected side of the tablet	"A 146" on bisected side of the tablet
THICKNESS: (Guideline)	3.1 mm	3.0 mm to 4.0 mm
WEIGHT VARIATION:	119.6 mg	± 10% Theo. Wt (120 mg) 108.0 mg - 132.0 mg
FRIABILITY:	0.1 %	NMT 1.0 %
IDENTIFICATION: (A)	the retention time of the major peak in the chromatogram of assay preparation corresponds to standard preparation.	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.25 mg	100.4 %	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) 101.4 % 6) 103.1 % 2) 102.0 % 7) 101.8 % 3) 103.1 % 8) 99.5 % 4) 102.1 % 9) 100.6 % 5) 100.3 % 10) 101.0 % AV: 101.5 % RSD: 1.2 %	85.0% to 115.0% RSD: NMT 6.0%

APPROVED BY S.D. 12/1/94

☑ COMPLIES

( ) DOES NOT COMPLY

PREPARED BY: Nilesh Patel DATE: 11/1/94

APPROVED BY: Sujaldevi Patel DATE: 11/1/94

8613-146c

Amide Pharmaceutical, Inc. Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets, 0.25 mg

SPECIFICATION: USP CONTROL #: 4330A

CHEMIST: K.A. VOLUME #: 326.01 PAGE #: 164 DATE: 12/11/94

SAMPLE STAGE: Overall composite of Batch Dated 11/29/94

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: 1, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) 78.7 % 7) 77.7 % 2) 80.1 % 8) 78.0 % 3) 81.9 % 9) 78.5 % 4) 79.8 % 10) 82.4 % 5) 77.9 % 11) 82.2 % 6) 80.1 % 12) 79.7 % Average: 79.8 % 60 minutes: 1) 91.2 % 7) 92.0 % 2) 92.0 % 8) 92.1 % 3) 91.0 % 9) 92.0 % 4) 91.6 % 10) 96.7 % 5) 91.9 % 11) 92.0 % 6) 93.2 % 12) 93.7 % Average: 92.5 %	(Note - the specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of digoxin dissolved in 60 minutes. If the amount of digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual tablet. (LC: Labeled amount) APPROVED BY [illegible] DATE 12/11/94
(X) COMPLIES ( ) DOES NOT COMPLY	PREPARED BY: Nilesh Patel DATE: 11/11/94 APPROVED BY: Surjanth Patel DATE: 11/11/94	

dc13-1186

Amide Pharmaceutical, Inc. Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets 0.25 mg

SPECIFICATION: USP CONTROL #: 4336 A

CHEMIST: ST/PK VOLUME #: 318-02/321-04 PAGE #: 41/268 DATE: 12/3/94

SAMPLE STAGE: Overall Composite dtd. 12/2/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	White	White
Profile:	Round Bisected Tablets	Round Bisected Tablets
Other: Debossed	"A 146" on bisected side of the tablet	"A 146" on bisected side of the tablet
THICKNESS: (Guideline)	3.1 mm	3.0 mm to 4.0 mm
WEIGHT VARIATION:	119.8 mg	± 10% Theo. wt (120 mg) 108.0 mg - 132.0 mg
FRIABILITY:	0.1%	NMT 1.0 %
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay Preparation corresponds to Standard Preparation.	The retention time of the major peak in the chromatogram of Assay prepration corresponds to standard prepration.
ASSAY: Digoxin, 0.25 mg	100.3%	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) 99.4 % 6) 99.9 % 2) 103.7 % 7) 101.2 % 3) 99.6 % 8) 99.7 % 4) 99.7 % 9) 99.6 % 5) 102.1 % 10) 99.3 % AV: 100.4 RSD: 1.5%	85.0% to 115.0% RSD: NMT 6.0%

APPROVED BY: [illegible] DATE: 12/5/94

( ) COMPLIES

( ) DOES NOT COMPLY

PREPARED BY: Nilesh Patel DATE: 11/1/94

APPROVED BY: Sujit Patel DATE: 11/1/94

0613-146c

Amide Pharmaceutical, Inc. Page 2 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets, 0.25 mg

SPECIFICATION: USP CONTROL #: 4336 A

CHEMIST: PA VOLUME #: 332-66 PAGE #: 136 DATE: 12/15/94

SAMPLE STAGE: Overall Composite dtd: 12/2/94

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: 1, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) 81.3 % 7) 79.1 % 2) 81.3 % 8) 82.1 % 3) 82.0 % 9) 80.3 % 4) 81.5 % 10) 80.9 % 5) 80.7 % 11) 80.1 % 6) 81.6 % 12) 80.1 % Average: 80.9 % 60 minutes: 1) 91.1 % 7) 93.9 % 2) 94.7 % 8) 92.7 % 3) 97.9 % 9) 91.7 % 4) 95.7 % 10) 96.5 % 5) 93.1 % 11) 94.8 % 6) 93.0 % 12) 93.1 % Average: 94.1 %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual tablet, the amount dissolved in 15 minutes is not more than 90% for each individual tablet. (LC: Labeled amount) APPROVED BY: [illegible] DATE: 12.5.94
(✓) COMPLIES ( ) DOES NOT COMPLY	PREPARED BY: Nilesh Patel DATE: 11/1/94 APPROVED BY: Suryakant Patel DATE: 11/1/94	

dc13-1486

Amide Pharmaceutical, Inc. Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets 0.25 mg

SPECIFICATION: USP CONTROL #: 4332A

CHEMIST: NP/P.K/K.A VOLUME #: 306.02/321.04/326.01 PAGE #: 8 11/12/94 44/281 DATE: 12/9/94

SAMPLE STAGE: Overall Composite of the Sample 177 Dated 12/8/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	white	White
Profile:	Round Bisected tablets	Round Bisected Tablets
Other: Debossed	"A146" on bisected side of the tablet	"A 146" on bisected side of the tablet
THICKNESS: (Guideline)	3.1 mm	3.0 mm to 4.0 mm
WEIGHT VARIATION:	129.1 mg	± 10% Theo. wt (120 mg) 108.0 mg – 132.0 mg
FRIABILITY:	0.1%	NMT 1.0 %
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay Prep. Corresponds to Std. Preparation.	The retention time of the major peak in the chromatogram of Assay prepration corresponds to standard prepration.
ASSAY: Digoxin, 0.25 mg	100.1%	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) 102.4 % 6) 98.8 % 2) 101.5 % 7) 96.4 % 3) 98.7 % 8) 98.5 % 4) 98.6 % 9) 95.9 % 5) 98.2 % 10) 101.3 % AV: 99.01 RSD: 2.1%	85.0% to 115.0% RSD: NMT 6.0%
APPROVED BY SD DATE 12/9		
(✓) COMPLIES	PREPARED BY: Nilesh Patel DATE: 11/1/94	
( ) DOES NOT COMPLY	APPROVED BY: Suzy Adam for Rao DATE: 11/1/94	

bc13-146c

Amide Pharmaceutical, Inc.

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets, 0.25 mg

SPECIFICATION: USP CONTROL #: 41337A

CHEMIST: K.A. VOLUME #: 326.01 PAGE #: 177 DATE: 12/9/94

SAMPLE STAGE: Overall composite of the batch DATE: 8/8/94

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I; rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) 74.8 % 7) 73.2 % 2) 73.6 % 8) 75.4 % 3) 75.6 % 9) 78.6 % 4) 75.2 % 10) 75.7 % 5) 80.0 % 11) 65.1 % 6) 63.8 % 12) 70.5 % Average: 73.9 % 60 minutes: 1) 91.8 % 7) 89.8 % 2) 89.4 % 8) 92.5 % 3) 90.4 % 9) 91.7 % 4) 89.1 % 10) 91.9 % 5) 97.5 % 11) 90.5 % 6) 98.1 % 12) 93.3 % Average: 92.2 %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual tablet, the amount dissolved in 15 minutes is not more than 90% for each individual tablet. (LC: Labeled amount)

APPROVED
BY S.D. DATE 12/9/94

☑ COMPLIES ( ) DOES NOT COMPLY	PREPARED BY: Nilesh Patel DATE: 11/1/94 APPROVED BY: Sujal Patel DATE: 11/1/94

qc13-146d

PROTOCOL No. 002

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL

DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV. 00

BATCH SIZE: 4,200,000 TABLETS

PREPARED BY: _____
Regulatory Affairs Director

DATE: 11/15/94

APPROVED BY:

_____
Manufacturing Operations Director

DATE: 11-16-94

_____
Quality Assurance Director

DATE: 11/17/94

_____
Quality Control Director

DATE: 11/16/94

_____
Vice President Operations

DATE: 11-16-94.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

PURPOSE:

This document provides the procedure to be followed to validate the manufacturing process for Digoxin Tablets 0.25 mg. It applies to the next three consecutive batches to be produced.

SCOPE:

This protocol is designed to be prospective in nature.

The guidelines presented here include all steps of the manufacturing process which may have an impact on product quality. They are as follows:

Raw Materials
Blending
Compression

Details of the process will be found in the completed copies of the Manufacturing Batch Records which are available in the file. A summary of the process is found on the attached flow chart. The major equipment used will be documented and monitored as described in the appropriate section below.

Temperature and humidity will be monitored in the production area on a daily basis.

2% excess of Digoxin is added in the finished product to compensate for production losses.

This product is manufactured by making three parts of the blend upto pre-lubrication stage in Blender #35. This is similar to the Digoxin 0.125 mg tablet strength which was previously validated. These parts will be combined and lubricated in blender #36. This will enable us to manufacture a larger batch. The blend for all the parts in Blender #35 will be sampled and tested along with the final blend in Blender #36.

The data gathered during the course of this study will be evaluated and any adjustments to the predetermined specifications or guidelines will be made as warranted based on the results of the three validation batches.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

PROCEDURE:

RAW MATERIALS

All raw materials used in a validation batch will be certified to meet all current Amide specifications for that item. These will specifically include particle size profile, bulk density, and tamped density.

Certification may be accomplished through direct testing by Amide, or an approved contract laboratory, or through a manufacturers Certificate of Analysis.

Digoxin, USP will be tested by Amide, or an approved contract laboratory for the complete monograph. This will include bulk density, tamped density, and particle size testing.

The excipients will be tested by Amide, or an approved contract laboratory, for those parameters required for expired stock retesting. In addition, particle size, bulk and tamped density will be run on all ingredients. The other results may be taken from the manufacturers COA.

In addition to the actual results, the name of the manufacturer, and the manufacturers lot number should be included in the report.

If more than one lot of a raw material is used in the production of the three batches the data should be evaluated to determine if any differences are detectable.

The acceptance criteria will be the specification limits for those tests listed in the Specification document.

BLENDING UNIFORMITY

The first preblend will be produced in the 3 cu.ft. Twin Shell Blender, (#32). The speed will be monitored and documented both empty and during blending.

The blend in this step will be subjected to further processing, no sampling will be taken at this point.

The second blend will be produced in the 10 Cu Ft. Twin Shell Blender, (#35). The speed will be monitored and documented both empty and during blending.

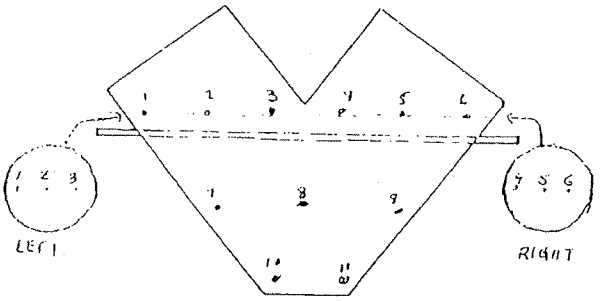
AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

The sampling plan for this blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. This is done to assure that complete blending is done since the next step is only lubrication. Samples are to be taken from the points shown below using only the 36 inch (small chamber) single port thief. The sample drawn should be about 350 mg which is three times the single dosage unit, and should be submitted to the laboratory in "Butter Paper."

SAMPLING POINTS

1. Left Column - Top left
2. Left Column - Top Center
3. Left Column - Top Right
4. Right Column - Top left
5. Right Column - Top Center
6. Right Column - Top Right
7. Middle - Left
8. Middle - Center
9. Middle - Right
10. Bottom - Left
11. Bottom - Right



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 116.5 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points. This product has a 2% overage to compensate for the production losses.

The final blend will be produced in the 56 Cu Ft. Double Cone Blender, PK, 21 rpm. (#22). The speed will be monitored and recorded.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

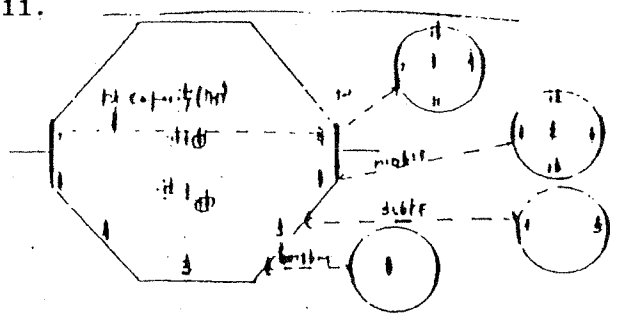
The sampling plan for the final blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. Samples about 360 mg are to be taken from the points shown below using only the 72 inch (small chamber) single port thief. This is required to approximate as close as possible to three times the dosage unit.

Three samples of about 150 g will be taken with the help of a stainless steel theif large chamber from the top center, middle center and bottom center of the blender. These sample will be tested for physical characterization which includes; bulk and tap density and particle size analysis. This data is for characterization only and these parameters will not be used to monitor routine production. Therefore, acceptance criteria will not be established.

SAMPLING POINTS

1. CENTER - Top
2. CENTER - Middle
3. CENTER - Bottom
4. LEFT - Slope
5. RIGHT - Slope
6. LEFT - Middle
7. LEFT - Top
8. RIGHT - Middle
9. RIGHT - Top
10. FRONT - Middle
11. FRONT - Top
12. REAR - Middle
13. REAR - Top

Note - On the diagram below points 12 and 13 are directly behind 10 and 11.



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 120.0 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points. This product has a 2% overage to compensate for the production losses.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

COMPRESSION

Compression will be accomplished using the stokes 45 station tablet press. The speed will be determined and documented during the validation study.

During compression samples will be collected every hour by QA. These samples will be evaluated for individual tablet weight, thickness, and hardness. This will be 10 tablets for weight, and five each for thickness and hardness. Front and rear samples will be tested separately and will not be composited for any test in this section unless specifically stated.

The hourly samples should be arranged chronologically and the batch divided into thirds. Each third should be evaluated as described below for all tests except content uniformity. The samples for each test should be prepared by selecting, as close as possible, an equal number of tablets from each hourly sample. If selecting one tablet per hour results in a greater number of tablets than the test requires the distribution should be as even as possible.

TEST	N
Friability	10 g - 1 Run
Disintegration	6
Dissolution	12 (6 front & 6 rear)

Content Uniformity testing is to be run across the entire batch. One tablet per hourly sample is to be run with a minimum of 30 tablets being required. The tablets selected for testing should be weighed prior to testing and their identity maintained. If compression runs for less than 30 hours, the additional tablets should be selected as evenly distributed as possible throughout the batch.

A portion of the blend will be run at hardness of 1.0 - 3.0 KP and above 8.0 KP. This will determine the effect of hardness on friability and dissolution.

Minimum quantities sufficient to equilibrate the press will be run at both lower and higher speeds. The actual ranges will be determined during production. Samples will be evaluated for hardness and weight.

Data analysis will consist of Average and Standard Deviation, with comparison both within and across the three batches. The data collected within each batch will also be evaluated for any possible trends.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.25 mg
MPR NO. 14602 REV.00

An overall composite sample will be prepared from all the hourly samples. This data will provide the basis for product release and will also be the initial data for stability.

Acceptance criteria will be as follows:

Target Weight (1 tablet):	120.0 mg
Target Weight (10 tablets):	1.200 g
Weight Range (1 tablet):	0.114 - 0.126 g
Thickness:	2.7 - 3.7 mm
Hardness:	2.0 - 8.0 KP
Friability	NMT 1%
Identification	Meets requirements.
Content Uniformity	85.0% - 115.0% (RSD NMT 6.0%)
Dissolution	Meets USP Requirement.
Assay	90.0 - 105.0%

AMIDE PHARMACEUTICAL, INC.

BATCH FLOW CHART FOR DIGOXIN TABLETS 0.25 mg
BATCH SIZE: 4,200,000 TABLETS
MPR # 14602, REV # 00

PART 1, 2 AND 3

10.353 kg Corn Starch, NF ----------> Twin Shell, 3Cu.Ft. Blender #32 Blend for 10 min with Intensifier bar ON.
0.357 kg Digoxin, USP ---------->
5.600 kg Croscarmellose Sodium, NF -------->

24.99 kg Lactose Hydrous, Impalpable, NF --> Twin Shell, 3Cu.Ft. Blender #32. Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF

35.00 kg Starch Pregelatinized, NF ---------> Twin Shell,10Cu.Ft. Blender #35 Blend for 10 min. with intensifier bar OFF
35.00 kg Microcrystalline Cellulose NF(101)>

51.80 kg Lactose Anhydrous, NF (DT) --------> Twin Shell,10Cu.Ft. Blender #35, Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF

(QA Blend Samples)

FINAL BLEND

12.60 kg Stearic Acid, NF ----------> Double Cone, PK 56 Cu.ft. Blender #22 Blend for 5 min.
2.100 kg Silicon Dioxide, NF ---------->
Part 1, 2 and 3---------->
(QA Final Blend Samples)

Compress Tablets ----------> Tablet Press Stokes 45 station
(QA Samples - Every hour)